

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To improve the bill.

**IN THE SENATE OF THE UNITED STATES—109th Cong., 1st Sess.**

**S. 1392**

To reauthorize the Federal Trade Commission.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. DORGAN

Viz:

1 At the appropriate place, insert the following:

2 **TITLE \_\_\_\_\_ —IMPORTATION OF**  
3 **PRESCRIPTION DRUGS**

4 **SEC. \_\_\_\_ 1. SHORT TITLE.**

5 This title may be cited as the “Pharmaceutical Mar-  
6 ket Access and Drug Safety Act of 2005”.

7 **SEC. \_\_\_\_ 2. FINDINGS.**

8 Congress finds that—

9 (1) Americans unjustly pay up to 5 times more  
10 to fill their prescriptions than consumers in other  
11 countries;

1           (2) the United States is the largest market for  
2           pharmaceuticals in the world, yet American con-  
3           sumers pay the highest prices for brand pharma-  
4           ceuticals in the world;

5           (3) a prescription drug is neither safe nor effec-  
6           tive to an individual who cannot afford it;

7           (4) allowing and structuring the importation of  
8           prescription drugs to ensure access to safe and af-  
9           fordable drugs approved by the Food and Drug Ad-  
10          ministration will provide a level of safety to Amer-  
11          ican consumers that they do not currently enjoy;

12          (5) American seniors alone will spend  
13          \$1,800,000,000,000 on pharmaceuticals over the  
14          next 10 years; and

15          (6) allowing open pharmaceutical markets could  
16          save American consumers at least \$38,000,000,000  
17          each year.

18 **SEC. \_\_\_\_ 3. REPEAL OF CERTAIN SECTION REGARDING IM-**

19 **PORTATION OF PRESCRIPTION DRUGS.**

20          Chapter VIII of the Federal Food, Drug, and Cos-  
21          metic Act (21 U.S.C. 381 et seq.) is amended by striking  
22          section 804.

1   **SEC. \_\_\_\_ 4. IMPORTATION OF PRESCRIPTION DRUGS; WAIV-**  
2                   **ER OF CERTAIN IMPORT RESTRICTIONS.**

3           (a) IN GENERAL.—Chapter VIII of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),  
5 as amended by section 3, is further amended by inserting  
6 after section 803 the following:

7   **“SEC. 804. COMMERCIAL AND PERSONAL IMPORTATION OF**  
8                   **PRESCRIPTION DRUGS.**

9           “(a) IMPORTATION OF PRESCRIPTION DRUGS.—

10               “(1) IN GENERAL.—In the case of qualifying  
11 drugs imported or offered for import into the United  
12 States from registered exporters or by registered im-  
13 porters—

14                       “(A) the limitation on importation that is  
15 established in section 801(d)(1) is waived; and

16                       “(B) the standards referred to in section  
17 801(a) regarding admission of the drugs are  
18 subject to subsection (g) of this section (includ-  
19 ing with respect to qualifying drugs to which  
20 section 801(d)(1) does not apply).

21           “(2) IMPORTERS.—A qualifying drug may not  
22 be imported under paragraph (1) unless—

23                       “(A) the drug is imported by a pharmacy,  
24 group of pharmacies, or a wholesaler that is a  
25 registered importer; or

1           “(B) the drug is imported by an individual  
2           for personal use or for the use of a family mem-  
3           ber of the individual (not for resale) from a reg-  
4           istered exporter.

5           “(3) RULE OF CONSTRUCTION.—This section  
6           shall apply only with respect to a drug that is im-  
7           ported or offered for import into the United  
8           States—

9           “(A) by a registered importer; or

10          “(B) from a registered exporter to an indi-  
11          vidual.

12          “(4) DEFINITIONS.—

13          “(A) REGISTERED EXPORTER; REG-  
14          ISTERED IMPORTER.—For purposes of this sec-  
15          tion:

16               “(i) The term ‘registered exporter’  
17               means an exporter for which a registration  
18               under subsection (b) has been approved  
19               and is in effect.

20               “(ii) The term ‘registered importer’  
21               means a pharmacy, group of pharmacies,  
22               or a wholesaler for which a registration  
23               under subsection (b) has been approved  
24               and is in effect.

1 “(iii) The term ‘registration condition’  
2 means a condition that must exist for a  
3 registration under subsection (b) to be ap-  
4 proved.

5 “(B) QUALIFYING DRUG.—For purposes of  
6 this section, the term ‘qualifying drug’ means a  
7 drug for which there is a corresponding U.S.  
8 label drug.

9 “(C) U.S. LABEL DRUG.—For purposes of  
10 this section, the term ‘U.S. label drug’ means  
11 a prescription drug that—

12 “(i) with respect to a qualifying drug,  
13 has the same active ingredient or ingredi-  
14 ents, route of administration, dosage form,  
15 and strength as the qualifying drug;

16 “(ii) with respect to the qualifying  
17 drug, is manufactured by or for the person  
18 that manufactures the qualifying drug;

19 “(iii) is approved under section  
20 505(c); and

21 “(iv) is not—

22 “(I) a controlled substance, as  
23 defined in section 102 of the Con-  
24 trolled Substances Act (21 U.S.C.  
25 802);

1 “(II) a biological product, as de-  
2 fined in section 351 of the Public  
3 Health Service Act (42 U.S.C. 262),  
4 including—

5 “(aa) a therapeutic DNA  
6 plasmid product;

7 “(bb) a therapeutic synthetic  
8 peptide product;

9 “(cc) a monoclonal antibody  
10 product for in vivo use; and

11 “(dd) a therapeutic recom-  
12 binant DNA-derived product;

13 “(III) an infused drug, including  
14 a peritoneal dialysis solution;

15 “(IV) an injected drug;

16 “(V) a drug that is inhaled dur-  
17 ing surgery;

18 “(VI) a drug that is the listed  
19 drug referred to in 2 or more abbrevi-  
20 ated new drug applications under  
21 which the drug is commercially mar-  
22 keted; or

23 “(VII) a sterile ophthalmic drug  
24 intended for topical use on or in the  
25 eye.

1                   “(D) OTHER DEFINITIONS.—For purposes  
2 of this section:

3                   “(i)(I) The term ‘exporter’ means a  
4 person that is in the business of exporting  
5 a drug to individuals in the United States  
6 from Canada or from a permitted country  
7 designated by the Secretary under sub-  
8 clause (II), or that, pursuant to submitting  
9 a registration under subsection (b), seeks  
10 to be in such business.

11                   “(II) The Secretary shall designate a  
12 permitted country under subparagraph (E)  
13 (other than Canada) as a country from  
14 which an exporter may export a drug to in-  
15 dividuals in the United States if the Sec-  
16 retary determines that—

17                   “(aa) the country has statutory  
18 or regulatory standards that are  
19 equivalent to the standards in the  
20 United States and Canada with re-  
21 spect to—

22                   “(AA) the training of phar-  
23 macists;

24                   “(BB) the practice of phar-  
25 macy; and

1 “(CC) the protection of the  
2 privacy of personal medical infor-  
3 mation; and

4 “(bb) the importation of drugs to  
5 individuals in the United States from  
6 the country will not adversely affect  
7 public health.

8 “(ii) The term ‘importer’ means a  
9 pharmacy, a group of pharmacies, or a  
10 wholesaler that is in the business of im-  
11 porting a drug into the United States or  
12 that, pursuant to submitting a registration  
13 under subsection (b), seeks to be in such  
14 business.

15 “(iii) The term ‘pharmacist’ means a  
16 person licensed by a State to practice  
17 pharmacy, including the dispensing and  
18 selling of prescription drugs.

19 “(iv) The term ‘pharmacy’ means a  
20 person that—

21 “(I) is licensed by a State to en-  
22 gage in the business of selling pre-  
23 scription drugs at retail; and

24 “(II) employs 1 or more phar-  
25 macists.



1 “(v) The term ‘prescription drug’  
2 means a drug that is described in section  
3 503(b)(1).

4 “(vi) The term ‘wholesaler’—  
5 “(I) means a person licensed as a  
6 wholesaler or distributor of prescrip-  
7 tion drugs in the United States under  
8 section 503(e)(2)(A); and

9 “(II) does not include a person  
10 authorized to import drugs under sec-  
11 tion 801(d)(1).

12 “(E) PERMITTED COUNTRY.—The term  
13 ‘permitted country’ means—

14 “(i) Australia;

15 “(ii) Canada;

16 “(iii) a member country of the Euro-  
17 pean Union, but does not include a mem-  
18 ber country with respect to which—

19 “(I) the country’s Annex to the  
20 Treaty of Accession to the European  
21 Union 2003 includes a transitional  
22 measure for the regulation of human  
23 pharmaceutical products that has not  
24 expired; or

1 “(II) the Secretary determines  
2 that the requirements described in  
3 subclauses (I) and (II) of clause (vii)  
4 will not be met by the date on which  
5 such transitional measure for the reg-  
6 ulation of human pharmaceutical  
7 products expires;

8 “(iv) Japan;

9 “(v) New Zealand;

10 “(vi) Switzerland; and

11 “(vii) a country in which the Sec-  
12 retary determines the following require-  
13 ments are met:

14 “(I) The country has statutory or  
15 regulatory requirements—

16 “(aa) that require the review  
17 of drugs for safety and effective-  
18 ness by an entity of the govern-  
19 ment of the country;

20 “(bb) that authorize the ap-  
21 proval of only those drugs that  
22 have been determined to be safe  
23 and effective by experts employed  
24 by or acting on behalf of such en-  
25 tity and qualified by scientific

1 training and experience to evalu-  
2 ate the safety and effectiveness of  
3 drugs on the basis of adequate  
4 and well-controlled investigations,  
5 including clinical investigations,  
6 conducted by experts qualified by  
7 scientific training and experience  
8 to evaluate the safety and effec-  
9 tiveness of drugs;

10 “(cc) that require the meth-  
11 ods used in, and the facilities and  
12 controls used for the manufac-  
13 ture, processing, and packing of  
14 drugs in the country to be ade-  
15 quate to preserve their identity,  
16 quality, purity, and strength;

17 “(dd) for the reporting of  
18 adverse reactions to drugs and  
19 procedures to withdraw approval  
20 and remove drugs found not to  
21 be safe or effective; and

22 “(ee) that require the label-  
23 ing and promotion of drugs to be  
24 in accordance with the approval  
25 of the drug.

1                   “(II) The valid marketing au-  
2                   thorization system in the country is  
3                   equivalent to the systems in the coun-  
4                   tries described in clauses (i) through  
5                   (vi).

6                   “(III) The importation of drugs  
7                   to the United States from the country  
8                   will not adversely affect public health.

9           “(b) REGISTRATION OF IMPORTERS AND EXPORT-  
10   ERS.—

11                   “(1) REGISTRATION OF IMPORTERS AND EX-  
12                   PORTERS.—A registration condition is that the im-  
13                   porter or exporter involved (referred to in this sub-  
14                   section as a ‘registrant’) submits to the Secretary a  
15                   registration containing the following:

16                           “(A)(i) In the case of an exporter, the  
17                           name of the exporter and an identification of all  
18                           places of business of the exporter that relate to  
19                           qualifying drugs, including each warehouse or  
20                           other facility owned or controlled by, or oper-  
21                           ated for, the exporter.

22                           “(ii) In the case of an importer, the name  
23                           of the importer and an identification of the  
24                           places of business of the importer at which the  
25                           importer initially receives a qualifying drug

1 after importation (which shall not exceed 3  
2 places of business except by permission of the  
3 Secretary).

4 “(B) Such information as the Secretary  
5 determines to be necessary to demonstrate that  
6 the registrant is in compliance with registration  
7 conditions under—

8 “(i) in the case of an importer, sub-  
9 sections (c), (d), (e), (g), and (j) (relating  
10 to the sources of imported qualifying  
11 drugs; the inspection of facilities of the im-  
12 porter; the payment of fees; compliance  
13 with the standards referred to in section  
14 801(a); and maintenance of records and  
15 samples); or

16 “(ii) in the case of an exporter, sub-  
17 sections (c), (d), (f), (g), (h), (i), and (j)  
18 (relating to the sources of exported quali-  
19 fying drugs; the inspection of facilities of  
20 the exporter and the marking of compliant  
21 shipments; the payment of fees; and com-  
22 pliance with the standards referred to in  
23 section 801(a); being licensed as a phar-  
24 macist; conditions for individual importa-

1                   tion; and maintenance of records and sam-  
2                   ples).

3                   “(C) An agreement by the registrant that  
4                   the registrant will not under subsection (a) im-  
5                   port or export any drug that is not a qualifying  
6                   drug.

7                   “(D) An agreement by the registrant to—

8                   “(i) notify the Secretary of a recall or  
9                   withdrawal of a qualifying drug distributed  
10                  in a permitted country that the registrant  
11                  has exported or imported, or intends to ex-  
12                  port or import, to the United States under  
13                  subsection (a);

14                 “(ii) provide for the return to the reg-  
15                 istrant of such drug; and

16                 “(iii) cease, or not begin, the expor-  
17                 tation or importation of such drug unless  
18                 the Secretary has notified the registrant  
19                 that exportation or importation of such  
20                 drug may proceed.

21                 “(E) An agreement by the registrant to  
22                 ensure and monitor compliance with each reg-  
23                 istration condition, to promptly correct any  
24                 noncompliance with such a condition, and to

1           promptly report to the Secretary any such non-  
2           compliance.

3           “(F) A plan describing the manner in  
4           which the registrant will comply with the agree-  
5           ment under subparagraph (E).

6           “(G) An agreement by the registrant to  
7           enforce a contract under subsection (c)(3)(B)  
8           against a party in the chain of custody of a  
9           qualifying drug with respect to the authority of  
10          the Secretary under clauses (ii) and (iii) of that  
11          subsection.

12          “(H) An agreement by the registrant to  
13          notify the Secretary not more than 30 days be-  
14          fore the registrant intends to make the change,  
15          of—

16                 “(i) any change that the registrant in-  
17                 tends to make regarding information pro-  
18                 vided under subparagraph (A) or (B); and

19                 “(ii) any change that the registrant  
20                 intends to make in the compliance plan  
21                 under subparagraph (F).

22          “(I) In the case of an exporter—

23                 “(i) An agreement by the exporter  
24                 that a qualifying drug will not under sub-  
25                 section (a) be exported to any individual

1 not authorized pursuant to subsection  
2 (a)(2)(B) to be an importer of such drug.

3 “(ii) An agreement to post a bond,  
4 payable to the Treasury of the United  
5 States that is equal in value to the lesser  
6 of—

7 “(I) the value of drugs exported  
8 by the exporter to the United States  
9 in a typical 4-week period over the  
10 course of a year under this section; or

11 “(II) \$1,000,000;

12 “(iii) An agreement by the exporter to  
13 comply with applicable provisions of Cana-  
14 dian law, or the law of the permitted coun-  
15 try designated under subsection  
16 (a)(4)(D)(i)(II) in which the exporter is lo-  
17 cated, that protect the privacy of personal  
18 information with respect to each individual  
19 importing a prescription drug from the ex-  
20 porter under subsection (a)(2)(B).

21 “(iv) An agreement by the exporter to  
22 report to the Secretary—

23 “(I) not later than August 1 of  
24 each fiscal year, the total price and  
25 the total volume of drugs exported to



1 the United States by the exporter dur-  
2 ing the 6-month period from January  
3 1 through June 30 of that year; and  
4 “(II) not later than January 1 of  
5 each fiscal year, the total price and  
6 the total volume of drugs exported to  
7 the United States by the exporter dur-  
8 ing the previous fiscal year.

9 “(J) In the case of an importer, an agree-  
10 ment by the importer to report to the Sec-  
11 retary—

12 “(i) not later than August 1 of each  
13 fiscal year, the total price and the total  
14 volume of drugs imported to the United  
15 States by the importer during the 6-month  
16 period from January 1 through June 30 of  
17 that fiscal year; and

18 “(ii) not later than January 1 of each  
19 fiscal year, the total price and the total  
20 volume of drugs imported to the United  
21 States by the importer during the previous  
22 fiscal year.

23 “(K) Such other provisions as the Sec-  
24 retary may require by regulation to protect the  
25 public health while permitting—

1 “(i) the importation by pharmacies,  
2 groups of pharmacies, and wholesalers as  
3 registered importers of qualifying drugs  
4 under subsection (a); and

5 “(ii) importation by individuals of  
6 qualifying drugs under subsection (a).

7 “(2) APPROVAL OR DISAPPROVAL OF REGISTRA-  
8 TION.—

9 “(A) IN GENERAL.—Not later than 90  
10 days after the date on which a registrant sub-  
11 mits to the Secretary a registration under para-  
12 graph (1), the Secretary shall notify the reg-  
13 istrant whether the registration is approved or  
14 is disapproved. The Secretary shall disapprove  
15 a registration if there is reason to believe that  
16 the registrant is not in compliance with one or  
17 more registration conditions, and shall notify  
18 the registrant of such reason. In the case of a  
19 disapproved registration, the Secretary shall  
20 subsequently notify the registrant that the reg-  
21 istration is approved if the Secretary deter-  
22 mines that the registrant is in compliance with  
23 such conditions.

24 “(B) CHANGES IN REGISTRATION INFOR-  
25 MATION.—Not later than 30 days after receiv-

1           ing a notice under paragraph (1)(H) from a  
2           registrant, the Secretary shall determine wheth-  
3           er the change involved affects the approval of  
4           the registration of the registrant under para-  
5           graph (1), and shall inform the registrant of  
6           the determination.

7           “(3) PUBLICATION OF CONTACT INFORMATION  
8           FOR REGISTERED EXPORTERS.—Through the Inter-  
9           net website of the Food and Drug Administration  
10          and a toll-free telephone number, the Secretary shall  
11          make readily available to the public a list of reg-  
12          istered exporters, including contact information for  
13          the exporters. Promptly after the approval of a reg-  
14          istration submitted under paragraph (1), the Sec-  
15          retary shall update the Internet website and the in-  
16          formation provided through the toll-free telephone  
17          number accordingly.

18          “(4) SUSPENSION AND TERMINATION.—

19                 “(A) SUSPENSION.—With respect to the  
20                 effectiveness of a registration submitted under  
21                 paragraph (1):

22                         “(i) Subject to clause (ii), the Sec-  
23                         retary may suspend the registration if the  
24                         Secretary determines, after notice and op-  
25                         portunity for a hearing, that the registrant

1 has failed to maintain substantial compli-  
2 ance with a registration condition.

3 “(ii) If the Secretary determines that,  
4 under color of the registration, the ex-  
5 porter has exported a drug or the importer  
6 has imported a drug that is not a quali-  
7 fying drug, or a drug that does not comply  
8 with subsection (g)(2)(A) or (g)(4), or has  
9 exported a qualifying drug to an individual  
10 in violation of subsection (i)(2)(F), the  
11 Secretary shall immediately suspend the  
12 registration. A suspension under the pre-  
13 ceding sentence is not subject to the provi-  
14 sion by the Secretary of prior notice, and  
15 the Secretary shall provide to the reg-  
16 istrant an opportunity for a hearing not  
17 later than 10 days after the date on which  
18 the registration is suspended.

19 “(iii) The Secretary may reinstate the  
20 registration, whether suspended under  
21 clause (i) or (ii), if the Secretary deter-  
22 mines that the registrant has demonstrated  
23 that further violations of registration con-  
24 ditions will not occur.

1                   “(B) TERMINATION.—The Secretary, after  
2                   notice and opportunity for a hearing, may ter-  
3                   minate the registration under paragraph (1) of  
4                   a registrant if the Secretary determines that  
5                   the registrant has engaged in a pattern or prac-  
6                   tice of violating 1 or more registration condi-  
7                   tions, or if on 1 or more occasions the Secretary  
8                   has under subparagraph (A)(ii) suspended the  
9                   registration of the registrant. The Secretary  
10                  may make the termination permanent, or for a  
11                  fixed period of not less than 1 year. During the  
12                  period in which the registration is terminated,  
13                  any registration submitted under paragraph (1)  
14                  by the registrant, or a person that is a partner  
15                  in the export or import enterprise, or a prin-  
16                  cipal officer in such enterprise, and any reg-  
17                  istration prepared with the assistance of the  
18                  registrant or such a person, has no legal effect  
19                  under this section.

20               “(5) DEFAULT OF BOND.—A bond required to  
21               be posted by an exporter under paragraph (1)(I)(ii)  
22               shall be defaulted and paid to the Treasury of the  
23               United States if, after opportunity for an informal  
24               hearing, the Secretary determines that the exporter  
25               has—

1           “(A) exported a drug to the United States  
2           that is not a qualifying drug or that is not in  
3           compliance with subsection (g)(2)(A), (g)(4), or  
4           (i); or

5           “(B) failed to permit the Secretary to con-  
6           duct an inspection described under subsection  
7           (d).

8           “(c) SOURCES OF QUALIFYING DRUGS.—A registra-  
9           tion condition is that the exporter or importer involved  
10          agrees that a qualifying drug will under subsection (a) be  
11          exported or imported into the United States only if there  
12          is compliance with the following:

13           “(1) The drug was manufactured in an estab-  
14          lishment—

15           “(A) required to register under subsection  
16          (h) or (i) of section 510; and

17           “(B)(i) inspected by the Secretary; or

18           “(ii) for which the Secretary has elected to  
19          rely on a satisfactory report of a good manufac-  
20          turing practice inspection of the establishment  
21          from a permitted country whose regulatory sys-  
22          tem the Secretary recognizes as equivalent  
23          under a mutual recognition agreement, as pro-  
24          vided for under section 510(i)(3), section 803,  
25          or part 26 of title 21, Code of Federal Regula-

1           tions (or any corresponding successor rule or  
2           regulation).

3           “(2) The establishment is located in any coun-  
4           try, and the establishment manufactured the drug  
5           for distribution in the United States or for distribu-  
6           tion in 1 or more of the permitted countries (without  
7           regard to whether in addition the drug is manufac-  
8           tured for distribution in a foreign country that is  
9           not a permitted country).

10          “(3) The exporter or importer obtained the  
11          drug—

12                 “(A) directly from the establishment; or

13                 “(B) directly from an entity that, by con-  
14                 tract with the exporter or importer—

15                         “(i) provides to the exporter or im-  
16                         porter a statement (in such form and con-  
17                         taining such information as the Secretary  
18                         may require) that, for the chain of custody  
19                         from the establishment, identifies each  
20                         prior sale, purchase, or trade of the drug  
21                         (including the date of the transaction and  
22                         the names and addresses of all parties to  
23                         the transaction);

1                   “(ii) agrees to permit the Secretary to  
2                   inspect such statements and related  
3                   records to determine their accuracy;

4                   “(iii) agrees, with respect to the quali-  
5                   fying drugs involved, to permit the Sec-  
6                   retary to inspect warehouses and other fa-  
7                   cilities, including records, of the entity for  
8                   purposes of determining whether the facili-  
9                   ties are in compliance with any standards  
10                  under this Act that are applicable to facili-  
11                  ties of that type in the United States; and

12                  “(iv) has ensured, through such con-  
13                  tractual relationships as may be necessary,  
14                  that the Secretary has the same authority  
15                  regarding other parties in the chain of cus-  
16                  tody from the establishment that the Sec-  
17                  retary has under clauses (ii) and (iii) re-  
18                  garding such entity.

19                  “(4)(A) The foreign country from which the im-  
20                  porter will import the drug is a permitted country;  
21                  or

22                  “(B) The foreign country from which the ex-  
23                  porter will export the drug is the permitted country  
24                  in which the exporter is located.



1           “(5) During any period in which the drug was  
2           not in the control of the manufacturer of the drug,  
3           the drug did not enter any country that is not a per-  
4           mitted country.

5           “(6) The exporter or importer retains a sample  
6           of each lot of the drug sufficient for testing by the  
7           Secretary.

8           “(d) INSPECTION OF FACILITIES; MARKING OF SHIP-  
9           MENTS.—

10           “(1) INSPECTION OF FACILITIES.—A registra-  
11           tion condition is that, for the purpose of assisting  
12           the Secretary in determining whether the exporter  
13           involved is in compliance with all other registration  
14           conditions—

15                   “(A) the exporter agrees to permit the Sec-  
16           retary—

17                           “(i) to conduct onsite inspections, in-  
18                           cluding monitoring on a day-to-day basis,  
19                           of places of business of the exporter that  
20                           relate to qualifying drugs, including each  
21                           warehouse or other facility owned or con-  
22                           trolled by, or operated for, the exporter;

23                           “(ii) to have access, including on a  
24                           day-to-day basis, to—

1 “(I) records of the exporter that  
2 relate to the export of such drugs, in-  
3 cluding financial records; and

4 “(II) samples of such drugs;

5 “(iii) to carry out the duties described  
6 in paragraph (3); and

7 “(iv) to carry out any other functions  
8 determined by the Secretary to be nec-  
9 essary regarding the compliance of the ex-  
10 porter; and

11 “(B) the Secretary has assigned 1 or more  
12 employees of the Secretary to carry out the  
13 functions described in this subsection for the  
14 Secretary randomly, but not less than 12 times  
15 annually, on the premises of places of busi-  
16 nesses referred to in subparagraph (A)(i), and  
17 such an assignment remains in effect on a con-  
18 tinuous basis.

19 “(2) MARKING OF COMPLIANT SHIPMENTS.—A  
20 registration condition is that the exporter involved  
21 agrees to affix to each shipping container of quali-  
22 fying drugs exported under subsection (a) such  
23 markings as the Secretary determines to be nec-  
24 essary to identify the shipment as being in compli-

1       ance with all registration conditions. Markings under  
2       the preceding sentence shall—

3               “(A) be designed to prevent affixation of  
4               the markings to any shipping container that is  
5               not authorized to bear the markings; and

6               “(B) include anticounterfeiting or track-  
7               and-trace technologies, taking into account the  
8               economic and technical feasibility of those tech-  
9               nologies.

10              “(3) CERTAIN DUTIES RELATING TO EXPORT-  
11       ERS.—Duties of the Secretary with respect to an ex-  
12       porter include the following:

13              “(A) Inspecting, randomly, but not less  
14              than 12 times annually, the places of business  
15              of the exporter at which qualifying drugs are  
16              stored and from which qualifying drugs are  
17              shipped.

18              “(B) During the inspections under sub-  
19              paragraph (A), verifying the chain of custody of  
20              a statistically significant sample of qualifying  
21              drugs from the establishment in which the drug  
22              was manufactured to the exporter, which shall  
23              be accomplished or supplemented by the use of  
24              anticounterfeiting or track-and-trace tech-  
25              nologies, taking into account the economic and

1 technical feasibility of those technologies, except  
2 that a drug that lacks such technologies from  
3 the point of manufacture shall not for that rea-  
4 son be excluded from importation by an ex-  
5 porter.

6 “(C) Randomly reviewing records of ex-  
7 ports to individuals for the purpose of deter-  
8 mining whether the drugs are being imported  
9 by the individuals in accordance with the condi-  
10 tions under subsection (i). Such reviews shall be  
11 conducted in a manner that will result in a sta-  
12 tistically significant determination of compli-  
13 ance with all such conditions.

14 “(D) Monitoring the affixing of markings  
15 under paragraph (2).

16 “(E) Inspecting as the Secretary deter-  
17 mines is necessary the warehouses and other fa-  
18 cilities, including records, of other parties in the  
19 chain of custody of qualifying drugs.

20 “(F) Determining whether the exporter is  
21 in compliance with all other registration condi-  
22 tions.

23 “(4) PRIOR NOTICE OF SHIPMENTS.—A reg-  
24 istration condition is that, not less than 8 hours and  
25 not more than 5 days in advance of the time of the

1       importation of a shipment of qualifying drugs, the  
2       importer involved agrees to submit to the Secretary  
3       a notice with respect to the shipment of drugs to be  
4       imported or offered for import into the United  
5       States under subsection (a). A notice under the pre-  
6       ceding sentence shall include—

7               “(A) the name and complete contact infor-  
8               mation of the person submitting the notice;

9               “(B) the name and complete contact infor-  
10              mation of the importer involved;

11              “(C) the identity of the drug, including the  
12              established name of the drug, the quantity of  
13              the drug, and the lot number assigned by the  
14              manufacturer;

15              “(D) the identity of the manufacturer of  
16              the drug, including the identity of the establish-  
17              ment at which the drug was manufactured;

18              “(E) the country from which the drug is  
19              shipped;

20              “(F) the name and complete contact infor-  
21              mation for the shipper of the drug;

22              “(G) anticipated arrival information, in-  
23              cluding the port of arrival and crossing location  
24              within that port, and the date and time;

1                   “(H) a summary of the chain of custody of  
2                   the drug from the establishment in which the  
3                   drug was manufactured to the importer;

4                   “(I) a declaration as to whether the Sec-  
5                   retary has ordered that importation of the drug  
6                   from the permitted country cease under sub-  
7                   section (g)(2)(C) or (D); and

8                   “(J) such other information as the Sec-  
9                   retary may require by regulation.

10                  “(5) MARKING OF COMPLIANT SHIPMENTS.—A  
11                  registration condition is that the importer involved  
12                  agrees, before wholesale distribution (as defined in  
13                  section 503(e)) of a qualifying drug that has been  
14                  imported under subsection (a), to affix to each con-  
15                  tainer of such drug such markings or other tech-  
16                  nology as the Secretary determines necessary to  
17                  identify the shipment as being in compliance with all  
18                  registration conditions, except that the markings or  
19                  other technology shall not be required on a drug  
20                  that bears comparable, compatible markings or tech-  
21                  nology from the manufacturer of the drug. Markings  
22                  or other technology under the preceding sentence  
23                  shall—

24                         “(A) be designed to prevent affixation of  
25                         the markings or other technology to any con-

1 tainer that is not authorized to bear the mark-  
2 ings; and

3 “(B) shall include anticounterfeiting or  
4 track-and-trace technologies, taking into ac-  
5 count the economic and technical feasibility of  
6 such technologies.

7 “(6) CERTAIN DUTIES RELATING TO IMPORT-  
8 ERS.—Duties of the Secretary with respect to an im-  
9 porter include the following:

10 “(A) Inspecting, randomly, but not less  
11 than 12 times annually, the places of business  
12 of the importer at which a qualifying drug is  
13 initially received after importation.

14 “(B) During the inspections under sub-  
15 paragraph (A), verifying the chain of custody of  
16 a statistically significant sample of qualifying  
17 drugs from the establishment in which the drug  
18 was manufactured to the importer, which shall  
19 be accomplished or supplemented by the use of  
20 anticounterfeiting or track-and-trace tech-  
21 nologies, taking into account the economic and  
22 technical feasibility of those technologies, except  
23 that a drug that lacks such technologies from  
24 the point of manufacture shall not for that rea-

1           son be excluded from importation by an im-  
2           porter.

3           “(C) Reviewing notices under paragraph  
4           (4).

5           “(D) Inspecting as the Secretary deter-  
6           mines is necessary the warehouses and other fa-  
7           cilities, including records of other parties in the  
8           chain of custody of qualifying drugs.

9           “(E) Determining whether the importer is  
10          in compliance with all other registration condi-  
11          tions.

12         “(e) IMPORTER FEES.—

13                 “(1) REGISTRATION FEE.—A registration con-  
14                 dition is that the importer involved pays to the Sec-  
15                 retary a fee of \$10,000 due on the date on which  
16                 the importer first submits the registration to the  
17                 Secretary under subsection (b).

18                 “(2) INSPECTION FEE.—A registration condi-  
19                 tion is that the importer involved pays a fee to the  
20                 Secretary in accordance with this subsection. Such  
21                 fee shall be paid not later than October 1 and April  
22                 1 of each fiscal year in the amount provided for  
23                 under paragraph (3).

24                 “(3) AMOUNT OF INSPECTION FEE.—



1           “(A) AGGREGATE TOTAL OF FEES.—Not  
2 later than 30 days before the start of each fis-  
3 cal year, the Secretary, in consultation with the  
4 Secretary of Homeland Security and the Sec-  
5 retary of the Treasury, shall establish an aggre-  
6 gate total of fees to be collected under para-  
7 graph (2) for importers for that fiscal year that  
8 is sufficient, and not more than necessary, to  
9 pay the costs for that fiscal year of admin-  
10 istering this section with respect to registered  
11 importers, including the costs associated with—

12           “(i) inspecting the facilities of reg-  
13 istered importers, and of other entities in  
14 the chain of custody of a qualifying drug  
15 as necessary, under subsection (d)(6);

16           “(ii) developing, implementing, and  
17 operating under such subsection an elec-  
18 tronic system for submission and review of  
19 the notices required under subsection  
20 (d)(4) with respect to shipments of quali-  
21 fying drugs under subsection (a) to assess  
22 compliance with all registration conditions  
23 when such shipments are offered for im-  
24 port into the United States; and

1 “(iii) inspecting such shipments as  
2 necessary, when offered for import into the  
3 United States to determine if such a ship-  
4 ment should be refused admission under  
5 subsection (g)(5).

6 “(B) LIMITATION.—Subject to subpara-  
7 graph (C), the aggregate total of fees collected  
8 under paragraph (2) for a fiscal year shall not  
9 exceed 1 percent of the total price of qualifying  
10 drugs imported during that fiscal year into the  
11 United States by registered importers under  
12 subsection (a).

13 “(C) TOTAL PRICE OF DRUGS.—

14 “(i) ESTIMATE.—For the purposes of  
15 complying with the limitation described in  
16 subparagraph (B) when establishing under  
17 subparagraph (A) the aggregate total of  
18 fees to be collected under paragraph (2)  
19 for a fiscal year, the Secretary shall esti-  
20 mate the total price of qualifying drugs im-  
21 ported into the United States by registered  
22 importers during that fiscal year by adding  
23 the total price of qualifying drugs imported  
24 by each registered importer during the 6-  
25 month period from January 1 through

1 June 30 of the previous fiscal year, as re-  
2 ported to the Secretary by each registered  
3 importer under subsection (b)(1)(J).

4 “(ii) CALCULATION.—Not later than  
5 March 1 of the fiscal year that follows the  
6 fiscal year for which the estimate under  
7 clause (i) is made, the Secretary shall cal-  
8 culate the total price of qualifying drugs  
9 imported into the United States by reg-  
10 istered importers during that fiscal year by  
11 adding the total price of qualifying drugs  
12 imported by each registered importer dur-  
13 ing that fiscal year, as reported to the Sec-  
14 retary by each registered importer under  
15 subsection (b)(1)(J).

16 “(iii) ADJUSTMENT.—If the total  
17 price of qualifying drugs imported into the  
18 United States by registered importers dur-  
19 ing a fiscal year as calculated under clause  
20 (ii) is less than the aggregate total of fees  
21 collected under paragraph (2) for that fis-  
22 cal year, the Secretary shall provide for a  
23 pro-rata reduction in the fee due from each  
24 registered importer on April 1 of the sub-

1                   sequent fiscal year so that the limitation  
2                   described in subparagraph (B) is observed.

3                   “(D) INDIVIDUAL IMPORTER FEE.—Sub-  
4                   ject to the limitation described in subparagraph  
5                   (B), the fee under paragraph (2) to be paid on  
6                   October 1 and April 1 by an importer shall be  
7                   an amount that is proportional to a reasonable  
8                   estimate by the Secretary of the semiannual  
9                   share of the importer of the volume of quali-  
10                  fying drugs imported by importers under sub-  
11                  section (a).

12                  “(4) USE OF FEES.—

13                  “(A) IN GENERAL.—Subject to appropria-  
14                  tions Acts, fees collected by the Secretary under  
15                  paragraphs (1) and (2) shall be credited to the  
16                  appropriation account for salaries and expenses  
17                  of the Food and Drug Administration until ex-  
18                  pended (without fiscal year limitation), and the  
19                  Secretary may, in consultation with the Sec-  
20                  retary of Homeland Security and the Secretary  
21                  of the Treasury, transfer some proportion of  
22                  such fees to the appropriation account for sala-  
23                  ries and expenses of the Bureau of Customs  
24                  and Border Protection until expended (without  
25                  fiscal year limitation).

1           “(B) SOLE PURPOSE.—Fees collected by  
2           the Secretary under paragraphs (1) and (2) are  
3           only available to the Secretary and, if trans-  
4           ferred, to the Secretary of Homeland Security,  
5           and are for the sole purpose of paying the costs  
6           referred to in paragraph (3)(A).

7           “(5) COLLECTION OF FEES.—In any case where  
8           the Secretary does not receive payment of a fee as-  
9           sessed under paragraph (1) or (2) within 30 days  
10          after it is due, such fee shall be treated as a claim  
11          of the United States Government subject to sub-  
12          chapter II of chapter 37 of title 31, United States  
13          Code.

14          “(f) EXPORTER FEES.—

15               “(1) REGISTRATION FEE.—A registration con-  
16               dition is that the exporter involved pays to the Sec-  
17               retary a fee of \$10,000 due on the date on which  
18               the exporter first submits that registration to the  
19               Secretary under subsection (b).

20               “(2) INSPECTION FEE.—A registration condi-  
21               tion is that the exporter involved pays a fee to the  
22               Secretary in accordance with this subsection. Such  
23               fee shall be paid not later than October 1 and April  
24               1 of each fiscal year in the amount provided for  
25               under paragraph (3).

1 “(3) AMOUNT OF INSPECTION FEE.—

2 “(A) AGGREGATE TOTAL OF FEES.—Not  
3 later than 30 days before the start of each fis-  
4 cal year, the Secretary, in consultation with the  
5 Secretary of Homeland Security and the Sec-  
6 retary of the Treasury, shall establish an aggre-  
7 gate total of fees to be collected under para-  
8 graph (2) for exporters for that fiscal year that  
9 is sufficient, and not more than necessary, to  
10 pay the costs for that fiscal year of admin-  
11 istering this section with respect to registered  
12 exporters, including the costs associated with—

13 “(i) inspecting the facilities of reg-  
14 istered exporters, and of other entities in  
15 the chain of custody of a qualifying drug  
16 as necessary, under subsection (d)(3);

17 “(ii) developing, implementing, and  
18 operating under such subsection a system  
19 to screen marks on shipments of qualifying  
20 drugs under subsection (a) that indicate  
21 compliance with all registration conditions,  
22 when such shipments are offered for im-  
23 port into the United States; and

24 “(iii) screening such markings, and  
25 inspecting such shipments as necessary,

1           when offered for import into the United  
2           States to determine if such a shipment  
3           should be refused admission under sub-  
4           section (g)(5).

5           “(B) LIMITATION.—Subject to subpara-  
6           graph (C), the aggregate total of fees collected  
7           under paragraph (2) for a fiscal year shall not  
8           exceed 1 percent of the total price of qualifying  
9           drugs imported during that fiscal year into the  
10          United States by registered exporters under  
11          subsection (a).

12          “(C) TOTAL PRICE OF DRUGS.—

13               “(i) ESTIMATE.—For the purposes of  
14               complying with the limitation described in  
15               subparagraph (B) when establishing under  
16               subparagraph (A) the aggregate total of  
17               fees to be collected under paragraph (2)  
18               for a fiscal year, the Secretary shall esti-  
19               mate the total price of qualifying drugs im-  
20               ported into the United States by registered  
21               exporters during that fiscal year by adding  
22               the total price of qualifying drugs exported  
23               by each registered exporter during the 6-  
24               month period from January 1 through  
25               June 30 of the previous fiscal year, as re-

ported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

“(ii) CALCULATION.—Not later than March 1 of the fiscal year that follows the fiscal year for which the estimate under clause (i) is made, the Secretary shall calculate the total price of qualifying drugs imported into the United States by registered exporters during that fiscal year by adding the total price of qualifying drugs exported by each registered exporter during that fiscal year, as reported to the Secretary by each registered exporter under subsection (b)(1)(I)(iv).

“(iii) ADJUSTMENT.—If the total price of qualifying drugs imported into the United States by registered exporters during a fiscal year as calculated under clause (ii) is less than the aggregate total of fees collected under paragraph (2) for that fiscal year, the Secretary shall provide for a pro-rata reduction in the fee due from each registered exporter on April 1 of the subsequent fiscal year so that the limitation described in subparagraph (B) is observed.



1                   “(D) INDIVIDUAL EXPORTER FEE.—Sub-  
2                   ject to the limitation described in subparagraph  
3                   (B), the fee under paragraph (2) to be paid on  
4                   October 1 and April 1 by an exporter shall be  
5                   an amount that is proportional to a reasonable  
6                   estimate by the Secretary of the semiannual  
7                   share of the exporter of the volume of quali-  
8                   fying drugs exported by exporters under sub-  
9                   section (a).

10                  “(4) USE OF FEES.—

11                         “(A) IN GENERAL.—Subject to appropria-  
12                         tions Acts, fees collected by the Secretary under  
13                         paragraphs (1) and (2) shall be credited to the  
14                         appropriation account for salaries and expenses  
15                         of the Food and Drug Administration until ex-  
16                         pended (without fiscal year limitation), and the  
17                         Secretary may, in consultation with the Sec-  
18                         retary of Homeland Security and the Secretary  
19                         of the Treasury, transfer some proportion of  
20                         such fees to the appropriation account for sala-  
21                         ries and expenses of the Bureau of Customs  
22                         and Border Protection until expended (without  
23                         fiscal year limitation).

24                         “(B) SOLE PURPOSE.—Fees collected by  
25                         the Secretary under paragraphs (1) and (2) are

1           only available to the Secretary and, if trans-  
2           ferred, to the Secretary of Homeland Security,  
3           and are for the sole purpose of paying the costs  
4           referred to in paragraph (3)(A).

5           “(5) COLLECTION OF FEES.—In any case where  
6           the Secretary does not receive payment of a fee as-  
7           sessed under paragraph (1) or (2) within 30 days  
8           after it is due, such fee shall be treated as a claim  
9           of the United States Government subject to sub-  
10          chapter II of chapter 37 of title 31, United States  
11          Code.

12          “(g) COMPLIANCE WITH SECTION 801(A).—

13               “(1) IN GENERAL.—A registration condition is  
14               that each qualifying drug exported under subsection  
15               (a) by the registered exporter involved or imported  
16               under subsection (a) by the registered importer in-  
17               volved is in compliance with the standards referred  
18               to in section 801(a) regarding admission of the drug  
19               into the United States, subject to paragraphs (2),  
20               (3), and (4).

21          “(2) SECTION 505; APPROVAL STATUS.—

22               “(A) IN GENERAL.—A qualifying drug that  
23               is imported or offered for import under sub-  
24               section (a) shall comply with the conditions es-  
25               tablished in the approved application under sec-

1           tion 505(b) for the U.S. label drug as described  
2           under this subsection.

3                   “(B) NOTICE BY MANUFACTURER; GEN-  
4           ERAL PROVISIONS.—

5                   “(i) IN GENERAL.—The person that  
6           manufactures a qualifying drug that is, or  
7           will be, introduced for commercial distribu-  
8           tion in a permitted country shall in accord-  
9           ance with this paragraph submit to the  
10          Secretary a notice that—

11                   “(I) includes each difference in  
12          the qualifying drug from a condition  
13          established in the approved applica-  
14          tion for the U.S. label drug beyond—

15                   “(aa) the variations provided  
16          for in the application; and

17                   “(bb) any difference in label-  
18          ing (except ingredient labeling);  
19          or

20                   “(II) states that there is no dif-  
21          ference in the qualifying drug from a  
22          condition established in the approved  
23          application for the U.S. label drug be-  
24          yond—

1 “(aa) the variations provided  
2 for in the application; and

3 “(bb) any difference in label-  
4 ing (except ingredient labeling).

5 “(ii) INFORMATION IN NOTICE.—A  
6 notice under clause (i)(I) shall include the  
7 information that the Secretary may require  
8 under section 506A, any additional infor-  
9 mation the Secretary may require (which  
10 may include data on bioequivalence if such  
11 data are not required under section 506A),  
12 and, with respect to the permitted country  
13 that approved the qualifying drug for com-  
14 mercial distribution, or with respect to  
15 which such approval is sought, include the  
16 following:

17 “(I) The date on which the quali-  
18 fying drug with such difference was,  
19 or will be, introduced for commercial  
20 distribution in the permitted country.

21 “(II) Information demonstrating  
22 that the person submitting the notice  
23 has also notified the government of  
24 the permitted country in writing that  
25 the person is submitting to the Sec-

1                   retary a notice under clause (i)(I),  
2                   which notice describes the difference  
3                   in the qualifying drug from a condi-  
4                   tion established in the approved appli-  
5                   cation for the U.S. label drug.

“(III) The information that the person submitted or will submit to the government of the permitted country for purposes of obtaining approval for commercial distribution of the drug in the country which, if in a language other than English, shall be accompanied by an English translation verified to be complete and accurate, with the name, address, and a brief statement of the qualifications of the person that made the translation.

18 “(iii) CERTIFICATIONS.—The chief ex-  
19 ecutive officer and the chief medical officer  
20 of the manufacturer involved shall each  
21 certify in the notice under clause (i) that—

22 “(I) the information provided in  
23 the notice is complete and true; and

24 “(II) a copy of the notice has  
25 been provided to the Federal Trade

1 Commission and to the State attor-  
2 neys general.

3 “(iv) FEE.—If a notice submitted  
4 under clause (i) includes a difference that  
5 would, under section 506A, require the  
6 submission of a supplemental application if  
7 made as a change to the U.S. label drug,  
8 the person that submits the notice shall  
9 pay to the Secretary a fee in the same  
10 amount as would apply if the person were  
11 paying a fee pursuant to section  
12 736(a)(1)(A)(ii). Subject to appropriations  
13 Acts, fees collected by the Secretary under  
14 the preceding sentence are available only to  
15 the Secretary and are for the sole purpose  
16 of paying the costs of reviewing notices  
17 submitted under clause (i).

18 “(v) TIMING OF SUBMISSION OF NO-  
19 TICES.—

20 “(I) PRIOR APPROVAL NO-  
21 TICES.—A notice under clause (i) to  
22 which subparagraph (C) applies shall  
23 be submitted to the Secretary not  
24 later than 120 days before the quali-  
25 fying drug with the difference is intro-

1           duced for commercial distribution in a  
2           permitted country, unless the country  
3           requires that distribution of the quali-  
4           fying drug with the difference begin  
5           less than 120 days after the country  
6           requires the difference.

7                   “(II) OTHER APPROVAL NO-  
8           TICES.—A notice under clause (i) to  
9           which subparagraph (D) applies shall  
10          be submitted to the Secretary not  
11          later than the day on which the quali-  
12          fying drug with the difference is intro-  
13          duced for commercial distribution in a  
14          permitted country.

15                   “(III) OTHER NOTICES.—A no-  
16          tice under clause (i) to which subpara-  
17          graph (E) applies shall be submitted  
18          to the Secretary on the date that the  
19          qualifying drug is first introduced for  
20          commercial distribution in a permitted  
21          country and annually thereafter.

22                   “(vi) REVIEW BY SECRETARY.—

23                   “(I) IN GENERAL.—In this para-  
24          graph, the difference in a qualifying  
25          drug that is submitted in a notice

1 under clause (i) from the U.S. label  
2 drug shall be treated by the Secretary  
3 as if it were a manufacturing change  
4 to the U.S. label drug under section  
5 506A.

6 “(II) STANDARD OF REVIEW.—  
7 Except as provided in subclause (III),  
8 the Secretary shall review and approve  
9 or disapprove the difference in a no-  
10 tice submitted under clause (i), if re-  
11 quired under section 506A, using the  
12 safe and effective standard for ap-  
13 proving or disapproving a manufac-  
14 turing change under section 506A.

15 “(III) BIOEQUIVALENCE.—If the  
16 Secretary would approve the dif-  
17 ference in a notice submitted under  
18 clause (i) using the safe and effective  
19 standard under section 506A and if  
20 the Secretary determines that the  
21 qualifying drug is not bioequivalent to  
22 the U.S. label drug, the Secretary  
23 may—

24 “(aa) include in the labeling  
25 provided under paragraph (3) a



1 prominent advisory that the  
2 qualifying drug is safe and effective but is not bioequivalent to  
3 the U.S. label drug if the Secretary determines that such an  
4 advisory is necessary for health  
5 care practitioners and patients to  
6 use the qualifying drug safely  
7 and effectively; or

10 “(bb) decline to approve the  
11 difference if the Secretary determines that the availability of  
12 both the qualifying drug and the  
13 U.S. label drug would pose a  
14 threat to the public health.

16 “(IV) REVIEW BY THE SECRETARY.—The Secretary shall review  
17 and approve or disapprove the difference in a notice submitted under  
18 clause (i), if required under section  
19 506A, not later than 120 days after  
20 the date on which the notice is submitted.

24 “(V) ESTABLISHMENT INSPECTION.—If review of such difference  
25

1 would require an inspection of the es-  
2 tablishment in which the qualifying  
3 drug is manufactured—

4 “(aa) such inspection by the  
5 Secretary shall be authorized;  
6 and

7 “(bb) the Secretary may rely  
8 on a satisfactory report of a good  
9 manufacturing practice inspec-  
10 tion of the establishment from a  
11 permitted country whose regu-  
12 latory system the Secretary rec-  
13 ognizes as equivalent under a  
14 mutual recognition agreement, as  
15 provided under section 510(i)(3),  
16 section 803, or part 26 of title  
17 21, Code of Federal Regulations  
18 (or any corresponding successor  
19 rule or regulation).

20 “(vii) PUBLICATION OF INFORMATION  
21 ON NOTICES.—

22 “(I) IN GENERAL.—Through the  
23 Internet website of the Food and  
24 Drug Administration and a toll-free  
25 telephone number, the Secretary shall

1 readily make available to the public a  
2 list of notices submitted under clause  
3 (i).

4 “(II) CONTENTS.—The list under  
5 subclause (I) shall include the date on  
6 which a notice is submitted and  
7 whether—

8 “(aa) a notice is under re-  
9 view;

10 “(bb) the Secretary has or-  
11 dered that importation of the  
12 qualifying drug from a permitted  
13 country cease; or

14 “(cc) the importation of the  
15 drug is permitted under sub-  
16 section (a).

17 “(III) UPDATE.—The Secretary  
18 shall promptly update the Internet  
19 website with any changes to the list.

20 “(C) NOTICE; DRUG DIFFERENCE REQUIR-  
21 ING PRIOR APPROVAL.—In the case of a notice  
22 under subparagraph (B)(i) that includes a dif-  
23 ference that would, under section 506A(c) or  
24 (d)(3)(B)(i), require the approval of a supple-  
25 mental application before the difference could

1           be made to the U.S. label drug the following

2           shall occur:

“(i) Promptly after the notice is submitted, the Secretary shall notify registered exporters, registered importers, the Federal Trade Commission, and the State attorneys general that the notice has been submitted with respect to the qualifying drug involved.

“(ii) If the Secretary has not made a determination whether such a supplemental application regarding the U.S. label drug would be approved or disapproved by the date on which the qualifying drug involved is to be introduced for commercial distribution in a permitted country, the Secretary shall—

18 “(I) order that the importation of  
19 the qualifying drug involved from the  
20 permitted country not begin until the  
21 Secretary completes review of the no-  
22 tice; and

23 “(II) promptly notify registered  
24 exporters, registered importers, the

1 Federal Trade Commission, and the  
2 State attorneys general of the order.

3 “(iii) If the Secretary determines that  
4 such a supplemental application regarding  
5 the U.S. label drug would not be approved,  
6 the Secretary shall—

7 “(I) order that the importation of  
8 the qualifying drug involved from the  
9 permitted country cease, or provide  
10 that an order under clause (ii), if any,  
11 remains in effect;

12 “(II) notify the permitted coun-  
13 try that approved the qualifying drug  
14 for commercial distribution of the de-  
15 termination; and

16 “(III) promptly notify registered  
17 exporters, registered importers, the  
18 Federal Trade Commission, and the  
19 State attorneys general of the deter-  
20 mination.

21 “(iv) If the Secretary determines that  
22 such a supplemental application regarding  
23 the U.S. label drug would be approved, the  
24 Secretary shall—

1 “(I) vacate the order under  
2 clause (ii), if any;

3 “(II) consider the difference to  
4 be a variation provided for in the ap-  
5 proved application for the U.S. label  
6 drug;

7 “(III) permit importation of the  
8 qualifying drug under subsection (a);  
9 and

10 “(IV) promptly notify registered  
11 exporters, registered importers, the  
12 Federal Trade Commission, and the  
13 State attorneys general of the deter-  
14 mination.

15 “(D) NOTICE; DRUG DIFFERENCE NOT RE-  
16 QUIRING PRIOR APPROVAL.—In the case of a  
17 notice under subparagraph (B)(i) that includes  
18 a difference that would, under section  
19 506A(d)(3)(B)(ii), not require the approval of a  
20 supplemental application before the difference  
21 could be made to the U.S. label drug the fol-  
22 lowing shall occur:

23 “(i) During the period in which the  
24 notice is being reviewed by the Secretary,  
25 the authority under this subsection to im-

1 port the qualifying drug involved continues  
2 in effect.

3 “(ii) If the Secretary determines that  
4 such a supplemental application regarding  
5 the U.S. label drug would not be approved,  
6 the Secretary shall—

7 “(I) order that the importation of  
8 the qualifying drug involved from the  
9 permitted country cease;

10 “(II) notify the permitted coun-  
11 try that approved the qualifying drug  
12 for commercial distribution of the de-  
13 termination; and

14 “(III) promptly notify registered  
15 exporters, registered importers, the  
16 Federal Trade Commission, and the  
17 State attorneys general of the deter-  
18 mination.

19 “(iii) If the Secretary determines that  
20 such a supplemental application regarding  
21 the U.S. label drug would be approved, the  
22 difference shall be considered to be a vari-  
23 ation provided for in the approved applica-  
24 tion for the U.S. label drug.

1           “(E) NOTICE; DRUG DIFFERENCE NOT RE-  
2           QUIRING APPROVAL; NO DIFFERENCE.—In the  
3           case of a notice under subparagraph (B)(i) that  
4           includes a difference for which, under section  
5           506A(d)(1)(A), a supplemental application  
6           would not be required for the difference to be  
7           made to the U.S. label drug, or that states that  
8           there is no difference, the Secretary—

9           “(i) shall consider such difference to  
10          be a variation provided for in the approved  
11          application for the U.S. label drug;

12          “(ii) may not order that the importa-  
13          tion of the qualifying drug involved cease;  
14          and

15          “(iii) shall promptly notify registered  
16          exporters and registered importers.

17          “(F) DIFFERENCES IN ACTIVE INGRE-  
18          DIENT, ROUTE OF ADMINISTRATION, DOSAGE  
19          FORM, OR STRENGTH.—

20          “(i) IN GENERAL.—A person who  
21          manufactures a drug approved under sec-  
22          tion 505(b) shall submit an application  
23          under section 505(b) for approval of an-  
24          other drug that is manufactured for dis-  
25          tribution in a permitted country by or for



1 the person that manufactures the drug ap-  
2 proved under section 505(b) if—

3 “(I) there is no qualifying drug  
4 in commercial distribution in per-  
5 mitted countries whose combined pop-  
6 ulation represents at least 50 percent  
7 of the total population of all permitted  
8 countries with the same active ingre-  
9 dient or ingredients, route of adminis-  
10 tration, dosage form, and strength as  
11 the drug approved under section  
12 505(b); and

13 “(II) each active ingredient of  
14 the other drug is related to an active  
15 ingredient of the drug approved under  
16 section 505(b), as defined in clause  
17 (v).

18 “(ii) APPLICATION UNDER SECTION  
19 505(b).—The application under section  
20 505(b) required under clause (i) shall—

21 “(I) request approval of the other  
22 drug for the indication or indications  
23 for which the drug approved under  
24 section 505(b) is labeled;

1 “(II) include the information that  
2 the person submitted to the govern-  
3 ment of the permitted country for  
4 purposes of obtaining approval for  
5 commercial distribution of the other  
6 drug in that country, which if in a  
7 language other than English, shall be  
8 accompanied by an English trans-  
9 lation verified to be complete and ac-  
10 curate, with the name, address, and a  
11 brief statement of the qualifications of  
12 the person that made the translation;

13 “(III) include a right of reference  
14 to the application for the drug ap-  
15 proved under section 505(b); and

16 “(IV) include such additional in-  
17 formation as the Secretary may re-  
18 quire.

19 “(iii) TIMING OF SUBMISSION OF AP-  
20 PPLICATION.—An application under section  
21 505(b) required under clause (i) shall be  
22 submitted to the Secretary not later than  
23 the day on which the information referred  
24 to in clause (ii)(II) is submitted to the gov-  
25 ernment of the permitted country.

1 “(iv) NOTICE OF DECISION ON APPLI-  
2 CATION.—The Secretary shall promptly no-  
3 tify registered exporters, registered import-  
4 ers, the Federal Trade Commission, and  
5 the State attorneys general of a determina-  
6 tion to approve or to disapprove an appli-  
7 cation under section 505(b) required under  
8 clause (i).

9 “(v) RELATED ACTIVE INGREDI-  
10 ENTS.—For purposes of clause (i)(II), 2  
11 active ingredients are related if they are—

12 “(I) the same; or

13 “(II) different salts, esters, or  
14 complexes of the same moiety.

15 “(3) SECTION 502; LABELING.—

16 “(A) IMPORTATION BY REGISTERED IM-  
17 PORTER.—

18 “(i) IN GENERAL.—In the case of a  
19 qualifying drug that is imported or offered  
20 for import by a registered importer, such  
21 drug shall be considered to be in compli-  
22 ance with section 502 and the labeling re-  
23 quirements under the approved application  
24 for the U.S. label drug if the qualifying  
25 drug bears—

“(I) a copy of the labeling approved for the U.S. label drug under section 505, without regard to whether the copy bears any trademark involved;

“(II) the name of the manufacturer and location of the manufacturer;

“(III) the lot number assigned by  
the manufacturer;

“(IV) the name, location, and registration number of the importer; and

“(V) the National Drug Code number assigned to the qualifying drug by the Secretary.

1 for each active ingredient in the quali-  
2 fying drug;

3 “(II) not include the proprietary  
4 name of the U.S. label drug or any  
5 active ingredient thereof;

6 “(III) if required under para-  
7 graph (2)(B)(vi)(III), a prominent ad-  
8 visory that the qualifying drug is safe  
9 and effective but not bioequivalent to  
10 the U.S. label drug; and

11 “(IV) if the inactive ingredients  
12 of the qualifying drug are different  
13 from the inactive ingredients for the  
14 U.S. label drug, include—

15 “(aa) a prominent notice  
16 that the ingredients of the quali-  
17 fying drug differ from the ingre-  
18 dients of the U.S. label drug and  
19 that the qualifying drug must be  
20 dispensed with an advisory to  
21 people with allergies about this  
22 difference and a list of ingredi-  
23 ents; and

24 “(bb) a list of the ingredi-  
25 ents of the qualifying drug as

1 would be required under section  
2 502(e).

3 “(B) IMPORTATION BY INDIVIDUAL.—

4 “(i) IN GENERAL.—In the case of a  
5 qualifying drug that is imported or offered  
6 for import by a registered exporter to an  
7 individual, such drug shall be considered to  
8 be in compliance with section 502 and the  
9 labeling requirements under the approved  
10 application for the U.S. label drug if the  
11 packaging and labeling of the qualifying  
12 drug complies with all applicable regula-  
13 tions promulgated under sections 3 and 4  
14 of the Poison Prevention Packaging Act of  
15 1970 (15 U.S.C. 1471 et seq.) and the la-  
16 beling of the qualifying drug includes—

17 “(I) directions for use by the  
18 consumer;

19 “(II) the lot number assigned by  
20 the manufacturer;

21 “(III) the name and registration  
22 number of the exporter;

23 “(IV) if required under para-  
24 graph (2)(B)(vi)(III), a prominent ad-  
25 visory that the drug is safe and effec-

1           tive but not bioequivalent to the U.S.  
2           label drug;

3           “(V) if the inactive ingredients of  
4           the drug are different from the inactive  
5           ingredients for the U.S. label  
6           drug—

7                   “(aa) a prominent advisory  
8                   that persons with an allergy  
9                   should check the ingredient list  
10                  of the drug because the ingredi-  
11                  ents of the drug differ from the  
12                  ingredients of the U.S. label  
13                  drug; and

14                  “(bb) a list of the ingredi-  
15                  ents of the drug as would be re-  
16                  quired under section 502(e); and

17                  “(VI) a copy of any special label-  
18                  ing that would be required by the Sec-  
19                  retary had the U.S. label drug been  
20                  dispensed by a pharmacist in the  
21                  United States, without regard to  
22                  whether the special labeling bears any  
23                  trademark involved.

24                  “(ii) PACKAGING.—A qualifying drug  
25                  offered for import to an individual by an

1 exporter under this section that is pack-  
2 aged in a unit-of-use container (as those  
3 items are defined in the United States  
4 Pharmacopeia and National Formulary)  
5 shall not be repackaged, provided that—

6 “(I) the packaging complies with  
7 all applicable regulations under sec-  
8 tions 3 and 4 of the Poison Preven-  
9 tion Packaging Act of 1970 (15  
10 U.S.C. 1471 et seq.); or

11 “(II) the consumer consents to  
12 waive the requirements of such Act,  
13 after being informed that the pack-  
14 aging does not comply with such Act  
15 and that the exporter will provide the  
16 drug in packaging that is compliant at  
17 no additional cost.

18 “(iii) REQUEST FOR COPY OF SPECIAL  
19 LABELING AND INGREDIENT LIST.—The  
20 Secretary shall provide to the registered  
21 exporter involved a copy of the special la-  
22 beling, the advisory, and the ingredient list  
23 described under clause (i), upon request of  
24 the exporter.



1 “(iv) REQUESTED LABELING AND IN-  
2 GREDIENT LIST.—The labeling and ingre-  
3 dient list provided by the Secretary under  
4 clause (iii) shall—

5 “(I) include the established  
6 name, as defined in section 502(e)(3),  
7 for each active ingredient in the drug;  
8 and

9 “(II) not include the proprietary  
10 name of the U.S. label drug or any  
11 active ingredient thereof.

12 “(4) SECTION 501; ADULTERATION.—A quali-  
13 fying drug that is imported or offered for import  
14 under subsection (a) shall be considered to be in  
15 compliance with section 501 if the drug is in compli-  
16 ance with subsection (c).

17 “(5) STANDARDS FOR REFUSING ADMISSION.—  
18 A drug exported under subsection (a) from a reg-  
19 istered exporter or imported by a registered importer  
20 may be refused admission into the United States if  
21 1 or more of the following applies:

22 “(A) The drug is not a qualifying drug.

23 “(B) A notice for the drug required under  
24 paragraph (2)(B) has not been submitted to the  
25 Secretary.

1           “(C) The Secretary has ordered that im-  
2           portation of the drug from the permitted coun-  
3           try cease under paragraph (2) (C) or (D).

4           “(D) The drug does not comply with para-  
5           graph (3) or (4).

6           “(E) The shipping container appears dam-  
7           aged in a way that may affect the strength,  
8           quality, or purity of the drug.

9           “(F) The Secretary becomes aware that—

10           “(i) the drug may be counterfeit;

11           “(ii) the drug may have been pre-  
12           pared, packed, or held under insanitary  
13           conditions; or

14           “(iii) the methods used in, or the fa-  
15           cilities or controls used for, the manufac-  
16           turing, processing, packing, or holding of  
17           the drug do not conform to good manufac-  
18           turing practice.

19           “(G) The Secretary has obtained an in-  
20           junction under section 302 that prohibits the  
21           distribution of the drug in interstate commerce.

22           “(H) The Secretary has under section  
23           505(e) withdrawn approval of the drug.

24           “(I) The manufacturer of the drug has in-  
25           stituted a recall of the drug.

1           “(J) If the drug is imported or offered for  
2           import by a registered importer without submis-  
3           sion of a notice in accordance with subsection  
4           (d)(4).

5           “(K) If the drug is imported or offered for  
6           import from a registered exporter to an indi-  
7           vidual and 1 or more of the following applies:

8                   “(i) The shipping container for such  
9                   drug does not bear the markings required  
10                  under subsection (d)(2).

11                  “(ii) The markings on the shipping  
12                  container appear to be counterfeit.

13                  “(iii) The shipping container or mark-  
14                  ings appear to have been tampered with.

15           “(h) LICENSING AS PHARMACIST.—A registration  
16           condition is that the exporter involved agrees that a quali-  
17           fying drug will be exported to an individual only if the  
18           Secretary has verified that—

19                   “(1) the exporter is authorized under the law of  
20                   the permitted country in which the exporter is lo-  
21                   cated to dispense prescription drugs; and

22                   “(2) the exporter employs persons that are li-  
23                   censed under the law of the permitted country in  
24                   which the exporter is located to dispense prescription  
25                   drugs in sufficient number to dispense safely the

1 drugs exported by the exporter to individuals, and  
2 the exporter assigns to those persons responsibility  
3 for dispensing such drugs to individuals.

4 “(i) INDIVIDUALS; CONDITIONS FOR IMPORTA-  
5 TION.—

6 “(1) IN GENERAL.—For purposes of subsection  
7 (a)(2)(B), the importation of a qualifying drug by  
8 an individual is in accordance with this subsection if  
9 the following conditions are met:

10 “(A) The drug is accompanied by a copy of  
11 a prescription for the drug, which prescrip-  
12 tion—

13 “(i) is valid under applicable Federal  
14 and State laws; and

15 “(ii) was issued by a practitioner who,  
16 under the law of a State of which the indi-  
17 vidual is a resident, or in which the indi-  
18 vidual receives care from the practitioner  
19 who issues the prescription, is authorized  
20 to administer prescription drugs.

21 “(B) The drug is accompanied by a copy  
22 of the documentation that was required under  
23 the law or regulations of the permitted country  
24 in which the exporter is located, as a condition  
25 of dispensing the drug to the individual.

1           “(C) The copies referred to in subpara-  
2 graphs (A)(i) and (B) are marked in a manner  
3 sufficient—

4           “(i) to indicate that the prescription,  
5 and the equivalent document in the per-  
6 mitted country in which the exporter is lo-  
7 cated, have been filled; and

8           “(ii) to prevent a duplicative filling by  
9 another pharmacist.

10          “(D) The individual has provided to the  
11 registered exporter a complete list of all drugs  
12 used by the individual for review by the individ-  
13 uals who dispense the drug.

14          “(E) The quantity of the drug does not ex-  
15 ceed a 90-day supply.

16          “(F) The drug is not an ineligible subpart  
17 H drug. For purposes of this section, a pre-  
18 scription drug is an ‘ineligible subpart H drug’  
19 if the drug was approved by the Secretary  
20 under subpart H of part 314 of title 21, Code  
21 of Federal Regulations (relating to accelerated  
22 approval), with restrictions under section 520 of  
23 such part to assure safe use, and the Secretary  
24 has published in the Federal Register a notice  
25 that the Secretary has determined that good

1           cause exists to prohibit the drug from being im-  
2           ported pursuant to this subsection.

3           “(2) NOTICE REGARDING DRUG REFUSED AD-  
4           MISSION.—If a registered exporter ships a drug to  
5           an individual pursuant to subsection (a)(2)(B) and  
6           the drug is refused admission to the United States,  
7           a written notice shall be sent to the individual and  
8           to the exporter that informs the individual and the  
9           exporter of such refusal and the reason for the re-  
10          fusal.

11          “(j) MAINTENANCE OF RECORDS AND SAMPLES.—

12           “(1) IN GENERAL.—A registration condition is  
13          that the importer or exporter involved shall—

14           “(A) maintain records required under this  
15          section for not less than 2 years; and

16           “(B) maintain samples of each lot of a  
17          qualifying drug required under this section for  
18          not less than 2 years.

19          “(2) PLACE OF RECORD MAINTENANCE.—The  
20          records described under paragraph (1) shall be  
21          maintained—

22           “(A) in the case of an importer, at the  
23          place of business of the importer at which the  
24          importer initially receives the qualifying drug  
25          after importation; or

1                   “(B) in the case of an exporter, at the fa-  
2                   cility from which the exporter ships the quali-  
3                   fying drug to the United States.

4                   “(k) DRUG RECALLS.—

5                   “(1) MANUFACTURERS.—A person that manu-  
6                   factures a qualifying drug imported from a per-  
7                   mitted country under this section shall promptly in-  
8                   form the Secretary—

9                   “(A) if the drug is recalled or withdrawn  
10                  from the market in a permitted country;

11                  “(B) how the drug may be identified, in-  
12                  cluding lot number; and

13                  “(C) the reason for the recall or with-  
14                  drawal.

15                  “(2) SECRETARY.—With respect to each per-  
16                  mitted country, the Secretary shall—

17                  “(A) enter into an agreement with the gov-  
18                  ernment of the country to receive information  
19                  about recalls and withdrawals of qualifying  
20                  drugs in the country; or

21                  “(B) monitor recalls and withdrawals of  
22                  qualifying drugs in the country using any infor-  
23                  mation that is available to the public in any  
24                  media.

1           “(3) NOTICE.—The Secretary may notify, as  
2           appropriate, registered exporters, registered import-  
3           ers, wholesalers, pharmacies, or the public of a recall  
4           or withdrawal of a qualifying drug in a permitted  
5           country.

6           “(l) DRUG LABELING AND PACKAGING.—

7           “(1) IN GENERAL.—When a qualifying drug  
8           that is imported into the United States by an im-  
9           porter under subsection (a) is dispensed by a phar-  
10          macist to an individual, the pharmacist shall provide  
11          that the packaging and labeling of the drug complies  
12          with all applicable regulations promulgated under  
13          sections 3 and 4 of the Poison Prevention Packaging  
14          Act of 1970 (15 U.S.C. 1471 et seq.) and shall in-  
15          clude with any other labeling provided to the indi-  
16          vidual the following:

17                  “(A) The lot number assigned by the man-  
18          ufacturer.

19                  “(B) The name and registration number of  
20          the importer.

21                  “(C) If required under paragraph  
22          (2)(B)(vi)(III) of subsection (g), a prominent  
23          advisory that the drug is safe and effective but  
24          not bioequivalent to the U.S. label drug.



1                   “(D) If the inactive ingredients of the drug  
2                   are different from the inactive ingredients for  
3                   the U.S. label drug—

4                   “(i) a prominent advisory that persons  
5                   with allergies should check the ingredient  
6                   list of the drug because the ingredients of  
7                   the drug differ from the ingredients of the  
8                   U.S. label drug; and

9                   “(ii) a list of the ingredients of the  
10                  drug as would be required under section  
11                  502(e).

12                 “(2) PACKAGING.—A qualifying drug that is  
13                 packaged in a unit-of-use container (as those terms  
14                 are defined in the United States Pharmacopeia and  
15                 National Formulary) shall not be repackaged, pro-  
16                 vided that—

17                 “(A) the packaging complies with all appli-  
18                 cable regulations under sections 3 and 4 of the  
19                 Poison Prevention Packaging Act of 1970 (15  
20                 U.S.C. 1471 et seq.); or

21                 “(B) the consumer consents to waive the  
22                 requirements of such Act, after being informed  
23                 that the packaging does not comply with such  
24                 Act and that the pharmacist will provide the

1 drug in packaging that is compliant at no addi-  
2 tional cost.

3 “(m) CHARITABLE CONTRIBUTIONS.—Notwith-  
4 standing any other provision of this section, this section  
5 does not authorize the importation into the United States  
6 of a qualifying drug donated or otherwise supplied for free  
7 or at nominal cost by the manufacturer of the drug to  
8 a charitable or humanitarian organization, including the  
9 United Nations and affiliates, or to a government of a for-  
10 eign country.

11 “(n) UNFAIR AND DISCRIMINATORY ACTS AND PRAC-  
12 TICES.—

13 “(1) IN GENERAL.—It is unlawful for a manu-  
14 facturer, directly or indirectly (including by being a  
15 party to a licensing agreement or other agreement),  
16 to—

17 “(A) discriminate by charging a higher  
18 price for a prescription drug sold to a registered  
19 exporter or other person in a permitted country  
20 that exports a qualifying drug to the United  
21 States under this section than the price that is  
22 charged, inclusive of rebates or other incentives  
23 to the permitted country or other person, to an-  
24 other person that is in the same country and

1           that does not export a qualifying drug into the  
2           United States under this section;

3           “(B) discriminate by charging a higher  
4           price for a prescription drug sold to a registered  
5           importer or other person that distributes, sells,  
6           or uses a qualifying drug imported into the  
7           United States under this section than the price  
8           that is charged to another person in the United  
9           States that does not import a qualifying drug  
10          under this section, or that does not distribute,  
11          sell, or use such a drug;

12          “(C) discriminate by denying, restricting,  
13          or delaying supplies of a prescription drug to a  
14          registered exporter or other person in a per-  
15          mitted country that exports a qualifying drug to  
16          the United States under this section or to a  
17          registered importer or other person that distrib-  
18          utes, sells, or uses a qualifying drug imported  
19          into the United States under this section;

20          “(D) discriminate by publicly, privately, or  
21          otherwise refusing to do business with a reg-  
22          istered exporter or other person in a permitted  
23          country that exports a qualifying drug to the  
24          United States under this section or with a reg-  
25          istered importer or other person that distrib-

1           utes, sells, or uses a qualifying drug imported  
2           into the United States under this section;

3           “(E) knowingly fail to submit a notice  
4           under subsection (g)(2)(B)(i), knowingly fail to  
5           submit such a notice on or before the date spec-  
6           ified in subsection (g)(2)(B)(v) or as otherwise  
7           required under subsection (e) (3), (4), and (5)  
8           of section \_\_\_\_ 4 of the Pharmaceutical Market  
9           Access and Drug Safety Act of 2005, knowingly  
10          submit such a notice that makes a materially  
11          false, fictitious, or fraudulent statement, or  
12          knowingly fail to provide promptly any informa-  
13          tion requested by the Secretary to review such  
14          a notice;

15          “(F) knowingly fail to submit an applica-  
16          tion required under subsection (g)(2)(F), know-  
17          ingly fail to submit such an application on or  
18          before the date specified in subsection  
19          (g)(2)(F)(ii), knowingly submit such an applica-  
20          tion that makes a materially false, fictitious, or  
21          fraudulent statement, or knowingly fail to pro-  
22          vide promptly any information requested by the  
23          Secretary to review such an application;

24          “(G) cause there to be a difference (includ-  
25          ing a difference in active ingredient, route of

1 administration, dosage form, strength, formula-  
2 tion, manufacturing establishment, manufac-  
3 turing process, or person that manufactures the  
4 drug) between a prescription drug for distribu-  
5 tion in the United States and the drug for dis-  
6 tribution in a permitted country;

7 “(H) refuse to allow an inspection author-  
8 ized under this section of an establishment that  
9 manufactures a qualifying drug that is, or will  
10 be, introduced for commercial distribution in a  
11 permitted country;

12 “(I) fail to conform to the methods used  
13 in, or the facilities used for, the manufacturing,  
14 processing, packing, or holding of a qualifying  
15 drug that is, or will be, introduced for commer-  
16 cial distribution in a permitted country to good  
17 manufacturing practice under this Act;

18 “(J) become a party to a licensing agree-  
19 ment or other agreement related to a qualifying  
20 drug that fails to provide for compliance with  
21 all requirements of this section with respect to  
22 such drug;

23 “(K) enter into a contract that restricts,  
24 prohibits, or delays the importation of a quali-  
25 fying drug under this section;

1 “(L) engage in any other action to restrict,  
2 prohibit, or delay the importation of a quali-  
3 fying drug under this section; or

4 “(M) engage in any other action that the  
5 Federal Trade Commission determines to dis-  
6 criminate against a person that engages or at-  
7 tempts to engage in the importation of a quali-  
8 fying drug under this section.

9 “(2) AFFIRMATIVE DEFENSE.—

10 “(A) DISCRIMINATION.—It shall be an af-  
11 firmative defense to a charge that a manufac-  
12 turer has discriminated under subparagraph  
13 (A), (B), (C), (D), or (M) of paragraph (1) that  
14 the higher price charged for a prescription drug  
15 sold to a person, the denial, restriction, or delay  
16 of supplies of a prescription drug to a person,  
17 the refusal to do business with a person, or  
18 other discriminatory activity against a person,  
19 is not based, in whole or in part, on—

20 “(i) the person exporting or importing  
21 a qualifying drug into the United States  
22 under this section; or

23 “(ii) the person distributing, selling,  
24 or using a qualifying drug imported into  
25 the United States under this section.

1           “(B) DRUG DIFFERENCES.—It shall be an  
2           affirmative defense to a charge that a manufac-  
3           turer has caused there to be a difference de-  
4           scribed in subparagraph (G) of paragraph (1)  
5           that—

6                   “(i) the difference was required by the  
7                   country in which the drug is distributed;

8                   “(ii) the Secretary has determined  
9                   that the difference was necessary to im-  
10                  prove the safety or effectiveness of the  
11                  drug;

12                  “(iii) the person manufacturing the  
13                  drug for distribution in the United States  
14                  has given notice to the Secretary under  
15                  subsection (g)(2)(B)(i) that the drug for  
16                  distribution in the United States is not dif-  
17                  ferent from a drug for distribution in per-  
18                  mitted countries whose combined popu-  
19                  lation represents at least 50 percent of the  
20                  total population of all permitted countries;  
21                  or

22                  “(iv) the difference was not caused, in  
23                  whole or in part, for the purpose of re-  
24                  stricting importation of the drug into the  
25                  United States under this section.

1 “(3) EFFECT OF SUBSECTION.—

2 “(A) SALES IN OTHER COUNTRIES.—This  
3 subsection applies only to the sale or distribu-  
4 tion of a prescription drug in a country if the  
5 manufacturer of the drug chooses to sell or dis-  
6 tribute the drug in the country. Nothing in this  
7 subsection shall be construed to compel the  
8 manufacturer of a drug to distribute or sell the  
9 drug in a country.

10 “(B) DISCOUNTS TO INSURERS, HEALTH  
11 PLANS, PHARMACY BENEFIT MANAGERS, AND  
12 COVERED ENTITIES.—Nothing in this sub-  
13 section shall be construed to—

14 “(i) prevent or restrict a manufac-  
15 turer of a prescription drug from providing  
16 discounts to an insurer, health plan, phar-  
17 macy benefit manager in the United  
18 States, or covered entity in the drug dis-  
19 count program under section 340B of the  
20 Public Health Service Act (42 U.S.C.  
21 256b) in return for inclusion of the drug  
22 on a formulary;

23 “(ii) require that such discounts be  
24 made available to other purchasers of the  
25 prescription drug; or



1 “(iii) prevent or restrict any other  
2 measures taken by an insurer, health plan,  
3 or pharmacy benefit manager to encourage  
4 consumption of such prescription drug.

5 “(C) CHARITABLE CONTRIBUTIONS.—  
6 Nothing in this subsection shall be construed  
7 to—

8 “(i) prevent a manufacturer from do-  
9 nating a prescription drug, or supplying a  
10 prescription drug at nominal cost, to a  
11 charitable or humanitarian organization,  
12 including the United Nations and affili-  
13 ates, or to a government of a foreign coun-  
14 try; or

15 “(ii) apply to such donations or sup-  
16 plying of a prescription drug.

17 “(4) ENFORCEMENT.—

18 “(A) UNFAIR OR DECEPTIVE ACT OR PRAC-  
19 TICE.—A violation of this subsection shall be  
20 treated as a violation of a rule defining an un-  
21 fair or deceptive act or practice prescribed  
22 under section 18(a)(1)(B) of the Federal Trade  
23 Commission Act (15 U.S.C. 57a(a)(1)(B)).

24 “(B) ACTIONS BY THE COMMISSION.—The  
25 Federal Trade Commission—

1           “(i) shall enforce this subsection in  
2           the same manner, by the same means, and  
3           with the same jurisdiction, powers, and du-  
4           ties as though all applicable terms and pro-  
5           visions of the Federal Trade Commission  
6           Act (15 U.S.C. 41 et seq.) were incor-  
7           porated into and made a part of this sec-  
8           tion; and

9           “(ii) may seek monetary relief three-  
10          fold the damages sustained, in addition to  
11          any other remedy available to the Federal  
12          Trade Commission under the Federal  
13          Trade Commission Act (15 U.S.C. 41 et  
14          seq.).

15          “(5) ACTIONS BY STATES.—

16               “(A) IN GENERAL.—

17                   “(i) CIVIL ACTIONS.—In any case in  
18                   which the attorney general of a State has  
19                   reason to believe that an interest of the  
20                   residents of that State have been adversely  
21                   affected by any manufacturer that violates  
22                   paragraph (1), the attorney general of a  
23                   State may bring a civil action on behalf of  
24                   the residents of the State, and persons  
25                   doing business in the State, in a district

1 court of the United States of appropriate  
2 jurisdiction to—

3 “(I) enjoin that practice;

4 “(II) enforce compliance with  
5 this subsection;

6 “(III) obtain damages, restitu-  
7 tion, or other compensation on behalf  
8 of residents of the State and persons  
9 doing business in the State, including  
10 threefold the damages; or

11 “(IV) obtain such other relief as  
12 the court may consider to be appro-  
13 priate.

14 “(ii) NOTICE.—

15 “(I) IN GENERAL.—Before filing  
16 an action under clause (i), the attor-  
17 ney general of the State involved shall  
18 provide to the Federal Trade Commis-  
19 sion—

20 “(aa) written notice of that  
21 action; and

22 “(bb) a copy of the com-  
23 plaint for that action.

24 “(II) EXEMPTION.—Subclause  
25 (I) shall not apply with respect to the

1 filing of an action by an attorney gen-  
2 eral of a State under this paragraph,  
3 if the attorney general determines  
4 that it is not feasible to provide the  
5 notice described in that subclause be-  
6 fore filing of the action. In such case,  
7 the attorney general of a State shall  
8 provide notice and a copy of the com-  
9 plaint to the Federal Trade Commis-  
10 sion at the same time as the attorney  
11 general files the action.

12 “(B) INTERVENTION.—

13 “(i) IN GENERAL.—On receiving no-  
14 tice under subparagraph (A)(ii), the Fed-  
15 eral Trade Commission shall have the right  
16 to intervene in the action that is the sub-  
17 ject of the notice.

18 “(ii) EFFECT OF INTERVENTION.—If  
19 the Federal Trade Commission intervenes  
20 in an action under subparagraph (A), it  
21 shall have the right—

22 “(I) to be heard with respect to  
23 any matter that arises in that action;  
24 and

25 “(II) to file a petition for appeal.

1           “(C) CONSTRUCTION.—For purposes of  
2           bringing any civil action under subparagraph  
3           (A), nothing in this subsection shall be con-  
4           strued to prevent an attorney general of a State  
5           from exercising the powers conferred on the at-  
6           torney general by the laws of that State to—

7                       “(i) conduct investigations;

8                       “(ii) administer oaths or affirmations;

9                       or

10                      “(iii) compel the attendance of wit-  
11                      nesses or the production of documentary  
12                      and other evidence.

13           “(D) ACTIONS BY THE COMMISSION.—In  
14           any case in which an action is instituted by or  
15           on behalf of the Federal Trade Commission for  
16           a violation of paragraph (1), a State may not,  
17           during the pendency of that action, institute an  
18           action under subparagraph (A) for the same  
19           violation against any defendant named in the  
20           complaint in that action.

21           “(E) VENUE.—Any action brought under  
22           subparagraph (A) may be brought in the dis-  
23           trict court of the United States that meets ap-  
24           plicable requirements relating to venue under  
25           section 1391 of title 28, United States Code.

1           “(F) SERVICE OF PROCESS.—In an action  
2 brought under subparagraph (A), process may  
3 be served in any district in which the defend-  
4 ant—

5                   “(i) is an inhabitant; or

6                   “(ii) may be found.

7           “(G) MEASUREMENT OF DAMAGES.—In  
8 any action under this paragraph to enforce a  
9 cause of action under this subsection in which  
10 there has been a determination that a defend-  
11 ant has violated a provision of this subsection,  
12 damages may be proved and assessed in the ag-  
13 gregate by statistical or sampling methods, by  
14 the computation of illegal overcharges or by  
15 such other reasonable system of estimating ag-  
16 gregate damages as the court in its discretion  
17 may permit without the necessity of separately  
18 proving the individual claim of, or amount of  
19 damage to, persons on whose behalf the suit  
20 was brought.

21           “(H) EXCLUSION ON DUPLICATIVE RE-  
22 LIEF.—The district court shall exclude from the  
23 amount of monetary relief awarded in an action  
24 under this paragraph brought by the attorney  
25 general of a State any amount of monetary re-

1           lief which duplicates amounts which have been  
2           awarded for the same injury.

3           “(6) EFFECT ON ANTITRUST LAWS.—Nothing  
4           in this subsection shall be construed to modify, im-  
5           pair, or supersede the operation of the antitrust  
6           laws. For the purpose of this subsection, the term  
7           ‘antitrust laws’ has the meaning given it in the first  
8           section of the Clayton Act, except that it includes  
9           section 5 of the Federal Trade Commission Act to  
10          the extent that such section 5 applies to unfair  
11          methods of competition.

12          “(7) MANUFACTURER.—In this subsection, the  
13          term ‘manufacturer’ means any entity, including any  
14          affiliate or licensee of that entity, that is engaged  
15          in—

16               “(A) the production, preparation, propaga-  
17               tion, compounding, conversion, or processing of  
18               a prescription drug, either directly or indirectly  
19               by extraction from substances of natural origin,  
20               or independently by means of chemical syn-  
21               thesis, or by a combination of extraction and  
22               chemical synthesis; or

23               “(B) the packaging, repackaging, labeling,  
24               relabeling, or distribution of a prescription  
25               drug.”.

1 (b) PROHIBITED ACTS.—The Federal Food, Drug,  
2 and Cosmetic Act is amended—

3 (1) in section 301 (21 U.S.C. 331), by striking  
4 paragraph (aa) and inserting the following:

5 “(aa)(1) The sale or trade by a pharmacist, or by  
6 a business organization of which the pharmacist is a part,  
7 of a qualifying drug that under section 804(a)(2)(A) was  
8 imported by the pharmacist, other than—

9 “(A) a sale at retail made pursuant to dis-  
10 pensing the drug to a customer of the pharmacist or  
11 organization; or

12 “(B) a sale or trade of the drug to a pharmacy  
13 or a wholesaler registered to import drugs under sec-  
14 tion 804.

15 “(2) The sale or trade by an individual of a qualifying  
16 drug that under section 804(a)(2)(B) was imported by the  
17 individual.

18 “(3) The making of a materially false, fictitious, or  
19 fraudulent statement or representation, or a material  
20 omission, in a notice under clause (i) of section  
21 804(g)(2)(B) or in an application required under section  
22 804(g)(2)(F), or the failure to submit such a notice or  
23 application.

24 “(4) The importation of a drug in violation of a reg-  
25 istration condition or other requirement under section



1 804, the falsification of any record required to be main-  
2 tained, or provided to the Secretary, under such section,  
3 or the violation of any registration condition or other re-  
4 quirement under such section.”; and

5 (2) in section 303(a) (21 U.S.C. 333(a)), by  
6 striking paragraph (6) and inserting the following:

7 “(6) Notwithstanding subsection (a), any person that  
8 knowingly violates section 301(i) (2) or (3) or section  
9 301(aa)(4) shall be imprisoned not more than 10 years,  
10 or fined in accordance with title 18, United States Code,  
11 or both.”.

12 (c) AMENDMENT OF CERTAIN PROVISIONS.—

13 (1) IN GENERAL.—Section 801 of the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C. 381) is  
15 amended by striking subsection (g) and inserting the  
16 following:

17 “(g) With respect to a prescription drug that is im-  
18 ported or offered for import into the United States by an  
19 individual who is not in the business of such importation,  
20 that is not shipped by a registered exporter under section  
21 804, and that is refused admission under subsection (a),  
22 the Secretary shall notify the individual that—

23 “(1) the drug has been refused admission be-  
24 cause the drug was not a lawful import under sec-  
25 tion 804;

1           “(2) the drug is not otherwise subject to a  
2           waiver of the requirements of subsection (a);

3           “(3) the individual may under section 804 law-  
4           fully import certain prescription drugs from export-  
5           ers registered with the Secretary under section 804;  
6           and

7           “(4) the individual can find information about  
8           such importation, including a list of registered ex-  
9           porters, on the Internet website of the Food and  
10          Drug Administration or through a toll-free telephone  
11          number required under section 804.”.

12          (2) ESTABLISHMENT REGISTRATION.—Section  
13          510(i) of the Federal Food, Drug, and Cosmetic Act  
14          (21 U.S.C. 360(i)) is amended in paragraph (1) by  
15          inserting after “import into the United States” the  
16          following: “, including a drug that is, or may be, im-  
17          ported or offered for import into the United States  
18          under section 804,”.

19          (3) EFFECTIVE DATE.—The amendments made  
20          by this subsection shall take effect on the date that  
21          is 90 days after the date of enactment of this title.

22          (d) EXHAUSTION.—

23          (1) IN GENERAL.—Section 271 of title 35,  
24          United States Code, is amended—

1 (A) by redesignating subsections (h) and  
2 (i) as (i) and (j), respectively; and  
3 (B) by inserting after subsection (g) the  
4 following:

5 “(h) It shall not be an act of infringement to use,  
6 offer to sell, or sell within the United States or to import  
7 into the United States any patented invention under sec-  
8 tion 804 of the Federal Food, Drug, and Cosmetic Act  
9 that was first sold abroad by or under authority of the  
10 owner or licensee of such patent.”.

11 (2) RULE OF CONSTRUCTION.—Nothing in the  
12 amendment made by paragraph (1) shall be con-  
13 strued to affect the ability of a patent owner or li-  
14 censee to enforce their patent, subject to such  
15 amendment.

16 (e) EFFECT OF SECTION 804.—

17 (1) IN GENERAL.—Section 804 of the Federal  
18 Food, Drug, and Cosmetic Act, as added by sub-  
19 section (a), shall permit the importation of quali-  
20 fying drugs (as defined in such section 804) into the  
21 United States without regard to the status of the  
22 issuance of implementing regulations—

23 (A) from exporters registered under such  
24 section 804 on the date that is 90 days after  
25 the date of enactment of this title; and

1 (B) from permitted countries, as defined in  
2 such section 804, by importers registered under  
3 such section 804 on the date that is 1 year  
4 after the date of enactment of this title.

5 (2) REVIEW OF REGISTRATION BY CERTAIN EX-  
6 PORTERS.—

7 (A) REVIEW PRIORITY.—In the review of  
8 registrations submitted under subsection (b) of  
9 such section 804, registrations submitted by en-  
10 tities in Canada that are significant exporters  
11 of prescription drugs to individuals in the  
12 United States as of the date of enactment of  
13 this title will have priority during the 90 day  
14 period that begins on such date of enactment.

15 (B) PERIOD FOR REVIEW.—During such  
16 90-day period, the reference in subsection  
17 (b)(2)(A) of such section 804 to 90 days (relat-  
18 ing to approval or disapproval of registrations)  
19 is, as applied to such entities, deemed to be 30  
20 days.

21 (C) LIMITATION.—That an exporter in  
22 Canada exports, or has exported, prescription  
23 drugs to individuals in the United States on or  
24 before the date that is 90 days after the date  
25 of enactment of this title shall not serve as a

1 basis, in whole or in part, for disapproving a  
2 registration under such section 804 from the  
3 exporter.

4 (D) FIRST YEAR LIMIT ON NUMBER OF  
5 EXPORTERS.—During the 1-year period begin-  
6 ning on the date of enactment of this title, the  
7 Secretary of Health and Human Services (re-  
8 ferred to in this section as the “Secretary”)  
9 may limit the number of registered exporters  
10 under such section 804 to not less than 50, so  
11 long as the Secretary gives priority to those ex-  
12 porters with demonstrated ability to process a  
13 high volume of shipments of drugs to individ-  
14 uals in the United States.

15 (E) SECOND YEAR LIMIT ON NUMBER OF  
16 EXPORTERS.—During the 1-year period begin-  
17 ning on the date that is 1 year after the date  
18 of enactment of this title, the Secretary may  
19 limit the number of registered exporters under  
20 such section 804 to not less than 100, so long  
21 as the Secretary gives priority to those export-  
22 ers with demonstrated ability to process a high  
23 volume of shipments of drugs to individuals in  
24 the United States.

1 (F) FURTHER LIMIT ON NUMBER OF EX-  
2 PORTERS.—During any 1-year period beginning  
3 on a date that is 2 or more years after the date  
4 of enactment of this title, the Secretary may  
5 limit the number of registered exporters under  
6 such section 804 to not less than 25 more than  
7 the number of such exporters during the pre-  
8 vious 1-year period, so long as the Secretary  
9 gives priority to those exporters with dem-  
10 onstrated ability to process a high volume of  
11 shipments of drugs to individuals in the United  
12 States.

13 (3) LIMITS ON NUMBER OF IMPORTERS.—

14 (A) FIRST YEAR LIMIT ON NUMBER OF IM-  
15 PORTERS.—During the 1-year period beginning  
16 on the date that is 1 year after the date of en-  
17 actment of this title, the Secretary may limit  
18 the number of registered importers under such  
19 section 804 to not less than 100 (of which at  
20 least a significant number shall be groups of  
21 pharmacies, to the extent feasible given the ap-  
22 plications submitted by such groups), so long as  
23 the Secretary gives priority to those importers  
24 with demonstrated ability to process a high vol-

1           ume of shipments of drugs imported into the  
2           United States.

3                   (B) SECOND YEAR LIMIT ON NUMBER OF  
4           IMPORTERS.—During the 1-year period begin-  
5           ning on the date that is 2 years after the date  
6           of enactment of this title, the Secretary may  
7           limit the number of registered importers under  
8           such section 804 to not less than 200 (of which  
9           at least a significant number shall be groups of  
10          pharmacies, to the extent feasible given the ap-  
11          plications submitted by such groups), so long as  
12          the Secretary gives priority to those importers  
13          with demonstrated ability to process a high vol-  
14          ume of shipments of drugs into the United  
15          States.

16                   (C) FURTHER LIMIT ON NUMBER OF IM-  
17          PORTERS.—During any 1-year period beginning  
18          on a date that is 3 or more years after the date  
19          of enactment of this title, the Secretary may  
20          limit the number of registered importers under  
21          such section 804 to not less than 50 more (of  
22          which at least a significant number shall be  
23          groups of pharmacies, to the extent feasible  
24          given the applications submitted by such  
25          groups) than the number of such importers

1           during the previous 1-year period, so long as  
2           the Secretary gives priority to those importers  
3           with demonstrated ability to process a high vol-  
4           ume of shipments of drugs to the United  
5           States.

6           (4) NOTICES FOR DRUGS FOR IMPORT FROM  
7           CANADA.—The notice with respect to a qualifying  
8           drug introduced for commercial distribution in Can-  
9           ada as of the date of enactment of this title that is  
10          required under subsection (g)(2)(B)(i) of such sec-  
11          tion 804 shall be submitted to the Secretary not  
12          later than 30 days after the date of enactment of  
13          this title if—

14                (A) the U.S. label drug (as defined in such  
15                section 804) for the qualifying drug is 1 of the  
16                100 prescription drugs with the highest dollar  
17                volume of sales in the United States based on  
18                the 12 calendar month period most recently  
19                completed before the date of enactment of this  
20                title; or

21                (B) the notice is a notice under subsection  
22                (g)(2)(B)(i)(II) of such section 804.

23          (5) NOTICE FOR DRUGS FOR IMPORT FROM  
24          OTHER COUNTRIES.—The notice with respect to a  
25          qualifying drug introduced for commercial distribu-



1       tion in a permitted country other than Canada as of  
2       the date of enactment of this title that is required  
3       under subsection (g)(2)(B)(i) of such section 804  
4       shall be submitted to the Secretary not later than  
5       180 days after the date of enactment of this title  
6       if—

7               (A) the U.S. label drug for the qualifying  
8       drug is 1 of the 100 prescription drugs with the  
9       highest dollar volume of sales in the United  
10      States based on the 12 calendar month period  
11      that is first completed on the date that is 120  
12      days after the date of enactment of this title; or

13              (B) the notice is a notice under subsection  
14      (g)(2)(B)(i)(II) of such section 804.

15      (6) NOTICE FOR OTHER DRUGS FOR IMPORT.—

16              (A) GUIDANCE ON SUBMISSION DATES.—

17      The Secretary shall by guidance establish a se-  
18      ries of submission dates for the notices under  
19      subsection (g)(2)(B)(i) of such section 804 with  
20      respect to qualifying drugs introduced for com-  
21      mercial distribution as of the date of enactment  
22      of this title and that are not required to be sub-  
23      mitted under paragraph (4) or (5).

24              (B) CONSISTENT AND EFFICIENT USE OF  
25      RESOURCES.—The Secretary shall establish the

1           dates described under subparagraph (A) so that  
2           such notices described under subparagraph (A)  
3           are submitted and reviewed at a rate that al-  
4           lows consistent and efficient use of the re-  
5           sources and staff available to the Secretary for  
6           such reviews. The Secretary may condition the  
7           requirement to submit such a notice, and the  
8           review of such a notice, on the submission by a  
9           registered exporter or a registered importer to  
10          the Secretary of a notice that such exporter or  
11          importer intends to import such qualifying drug  
12          to the United States under such section 804.

13                 (C) PRIORITY FOR DRUGS WITH HIGHER  
14          SALES.—The Secretary shall establish the dates  
15          described under subparagraph (A) so that the  
16          Secretary reviews the notices described under  
17          such subparagraph with respect to qualifying  
18          drugs with higher dollar volume of sales in the  
19          United States before the notices with respect to  
20          drugs with lower sales in the United States.

21                 (7) NOTICES FOR DRUGS APPROVED AFTER EF-  
22          FECTIVE DATE.—The notice required under sub-  
23          section (g)(2)(B)(i) of such section 804 for a quali-  
24          fying drug first introduced for commercial distribu-  
25          tion in a permitted country (as defined in such sec-

1       tion 804) after the date of enactment of this title  
2       shall be submitted to and reviewed by the Secretary  
3       as provided under subsection (g)(2)(B) of such sec-  
4       tion 804, without regard to paragraph (4), (5), or  
5       (6).

6           (8) REPORT.—Beginning with fiscal year 2006,  
7       not later than 90 days after the end of each fiscal  
8       year during which the Secretary reviews a notice re-  
9       ferred to in paragraph (4), (5), or (6), the Secretary  
10      shall submit a report to Congress concerning the  
11      progress of the Food and Drug Administration in re-  
12      viewing the notices referred to in paragraphs (4),  
13      (5), and (6).

14           (9) USER FEES.—

15           (A) EXPORTERS.—When establishing an  
16      aggregate total of fees to be collected from ex-  
17      porters under subsection (f)(2) of such section  
18      804, the Secretary shall, under subsection  
19      (f)(3)(C)(i) of such section 804, estimate the  
20      total price of drugs imported under subsection  
21      (a) of such section 804 into the United States  
22      by registered exporters during fiscal year 2006  
23      to be \$1,000,000,000.

24           (B) IMPORTERS.—When establishing an  
25      aggregate total of fees to be collected from im-

1 porters under subsection (e)(2) of such section  
2 804, the Secretary shall, under subsection  
3 (e)(3)(C)(i) of such section 804, estimate the  
4 total price of drugs imported under subsection  
5 (a) of such section 804 into the United States  
6 by registered importers during—

7 (i) fiscal year 2006 to be  
8 \$1,000,000,000; and

9 (ii) fiscal year 2007 to be  
10 \$10,000,000,000.

11 (C) FISCAL YEAR 2007 ADJUSTMENT.—

12 (i) REPORTS.—Not later than Feb-  
13 ruary 20, 2007, registered importers shall  
14 report to the Secretary the total price and  
15 the total volume of drugs imported to the  
16 United States by the importer during the  
17 4-month period from October 1, 2006,  
18 through January 31, 2007.

19 (ii) REESTIMATE.—Notwithstanding  
20 subsection (e)(3)(C)(ii) of such section 804  
21 or subparagraph (B), the Secretary shall  
22 reestimate the total price of qualifying  
23 drugs imported under subsection (a) of  
24 such section 804 into the United States by

1 registered importers during fiscal year  
2 2007. Such reestimate shall be equal to—

3 (I) the total price of qualifying  
4 drugs imported by each importer as  
5 reported under clause (i); multiplied  
6 by

7 (II) 3.

8 (iii) ADJUSTMENT.—The Secretary  
9 shall adjust the fee due on April 1, 2007,  
10 from each importer so that the aggregate  
11 total of fees collected under subsection  
12 (e)(2) for fiscal year 2007 does not exceed  
13 the total price of qualifying drugs imported  
14 under subsection (a) of such section 804  
15 into the United States by registered im-  
16 porters during fiscal year 2007 as reesti-  
17 mated under clause (ii).

18 (D) ANNUAL REPORT.—

19 (i) FOOD AND DRUG ADMINISTRA-  
20 TION.—Beginning with fiscal year 2006,  
21 not later than 180 days after the end of  
22 each fiscal year during which fees are col-  
23 lected under subsection (e), (f), or  
24 (g)(2)(B)(iv) of such section 804, the Sec-  
25 retary shall prepare and submit to the

1 House of Representatives and the Senate a  
2 report on the implementation of the au-  
3 thority for such fees during such fiscal  
4 year and the use, by the Food and Drug  
5 Administration, of the fees collected for the  
6 fiscal year for which the report is made  
7 and credited to the Food and Drug Admin-  
8 istration.

9 (ii) CUSTOMS AND BORDER CON-  
10 TROL.—Beginning with fiscal year 2006,  
11 not later than 180 days after the end of  
12 each fiscal year during which fees are col-  
13 lected under subsection (e) or (f) of such  
14 section 804, the Secretary of Homeland  
15 Security, in consultation with the Sec-  
16 retary of the Treasury, shall prepare and  
17 submit to the House of Representatives  
18 and the Senate a report on the use, by the  
19 Bureau of Customs and Border Protection,  
20 of the fees, if any, transferred by the Sec-  
21 retary to the Bureau of Customs and Bor-  
22 der Protection for the fiscal year for which  
23 the report is made.

24 (f) IMPLEMENTATION OF SECTION 804.—

1           (1) INTERIM RULE.—The Secretary may pro-  
2           mulgate an interim rule for implementing section  
3           804 of the Federal Food, Drug, and Cosmetic Act,  
4           as added by subsection (a) of this section.

5           (2) NO NOTICE OF PROPOSED RULEMAKING.—  
6           The interim rule described under paragraph (1) may  
7           be developed and promulgated by the Secretary with-  
8           out providing general notice of proposed rulemaking.

9           (3) FINAL RULE.—Not later than 1 year after  
10          the date on which the Secretary promulgates an in-  
11          terim rule under paragraph (1), the Secretary shall,  
12          in accordance with procedures under section 553 of  
13          title 5, United States Code, promulgate a final rule  
14          for implementing such section 804, which may incor-  
15          porate by reference provisions of the interim rule  
16          provided for under paragraph (1), to the extent that  
17          such provisions are not modified.

18          (g) CONSUMER EDUCATION.—The Secretary shall  
19          carry out activities that educate consumers—

20                (1) with regard to the availability of qualifying  
21                drugs for import for personal use from an exporter  
22                registered with and approved by the Food and Drug  
23                Administration under section 804 of the Federal  
24                Food, Drug, and Cosmetic Act, as added by this sec-  
25                tion, including information on how to verify whether

1 an exporter is registered and approved by use of the  
2 Internet website of the Food and Drug Administra-  
3 tion and the toll-free telephone number required by  
4 this title;

5 (2) that drugs that consumers attempt to im-  
6 port from an exporter that is not registered with and  
7 approved by the Food and Drug Administration can  
8 be seized by the United States Customs Service and  
9 destroyed, and that such drugs may be counterfeit,  
10 unapproved, unsafe, or ineffective; and

11 (3) with regard to the availability at domestic  
12 retail pharmacies of qualifying drugs imported under  
13 such section 804 by domestic wholesalers and phar-  
14 macies registered with and approved by the Food  
15 and Drug Administration.

16 (h) EFFECT ON ADMINISTRATION PRACTICES.—Not-  
17 withstanding any provision of this title (and the amend-  
18 ments made by this title), nothing in this title (or the  
19 amendments made by this title) shall be construed to  
20 change, limit, or restrict the practices of the Food and  
21 Drug Administration or the Bureau of Customs and Bor-  
22 der Protection in effect on January 1, 2004, with respect  
23 to the importation of prescription drugs into the United  
24 States by an individual, on the person of such individual,  
25 for personal use.



1   **SEC. \_\_\_\_ 5. DISPOSITION OF CERTAIN DRUGS DENIED AD-**  
2                   **MISSION INTO UNITED STATES.**

3           (a) IN GENERAL.—Chapter VIII of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.),  
5 as amended by section \_\_\_\_ 3, is further amended by add-  
6 ing at the end the following section:

7   **“SEC. 805. DISPOSITION OF CERTAIN DRUGS DENIED AD-**  
8                   **MISSION.**

9           “(a) IN GENERAL.—The Secretary of Homeland Se-  
10 curity shall deliver to the Secretary a shipment of drugs  
11 that is imported or offered for import into the United  
12 States if—

13               “(1) the shipment has a declared value of less  
14           than \$10,000; and

15               “(2)(A) the shipping container for such drugs  
16           does not bear the markings required under section  
17           804(d)(2); or

18               “(B) the Secretary has requested delivery of  
19           such shipment of drugs.

20           “(b) NO BOND OR EXPORT.—Section 801(b) does  
21 not authorize the delivery to the owner or consignee of  
22 drugs delivered to the Secretary under subsection (a) pur-  
23 suant to the execution of a bond, and such drugs may not  
24 be exported.

25           “(c) DESTRUCTION OF VIOLATIVE SHIPMENT.—The  
26 Secretary shall destroy a shipment of drugs delivered by

1 the Secretary of Homeland Security to the Secretary  
2 under subsection (a) if—

3 “(1) in the case of drugs that are imported or  
4 offered for import from a registered exporter under  
5 section 804, the drugs are in violation of any stand-  
6 ard described in section 804(g)(5); or

7 “(2) in the case of drugs that are not imported  
8 or offered for import from a registered exporter  
9 under section 804, the drugs are in violation of a  
10 standard referred to in section 801(a) or 801(d)(1).

11 “(d) CERTAIN PROCEDURES.—

12 “(1) IN GENERAL.—The delivery and destruc-  
13 tion of drugs under this section may be carried out  
14 without notice to the importer, owner, or consignee  
15 of the drugs except as required by section 801(g) or  
16 section 804(i)(2). The issuance of receipts for the  
17 drugs, and recordkeeping activities regarding the  
18 drugs, may be carried out on a summary basis.

19 “(2) OBJECTIVE OF PROCEDURES.—Procedures  
20 promulgated under paragraph (1) shall be designed  
21 toward the objective of ensuring that, with respect to  
22 efficiently utilizing Federal resources available for  
23 carrying out this section, a substantial majority of  
24 shipments of drugs subject to described in sub-  
25 section (c) are identified and destroyed.

1       “(e) EVIDENCE EXCEPTION.—Drugs may not be de-  
2 stroyed under subsection (c) to the extent that the Attor-  
3 ney General of the United States determines that the  
4 drugs should be preserved as evidence or potential evi-  
5 dence with respect to an offense against the United States.

6       “(f) RULE OF CONSTRUCTION.—This section may  
7 not be construed as having any legal effect on applicable  
8 law with respect to a shipment of drugs that is imported  
9 or offered for import into the United States and has a  
10 declared value equal to or greater than \$10,000.”.

11       (b) PROCEDURES.—Procedures for carrying out sec-  
12 tion 805 of the Federal Food, Drug, and Cosmetic Act,  
13 as added by subsection (a), shall be established not later  
14 than 90 days after the date of the enactment of this title.

15       (c) EFFECTIVE DATE.—The amendments made by  
16 this section shall take effect on the date that is 90 days  
17 after the date of enactment of this title.

18 **SEC. \_\_\_\_ 6. WHOLESALE DISTRIBUTION OF DRUGS; STATE-**  
19 **MENTS REGARDING PRIOR SALE, PURCHASE,**  
20 **OR TRADE.**

21       (a) STRIKING OF EXEMPTIONS; APPLICABILITY TO  
22 REGISTERED EXPORTERS.—Section 503(e) of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is  
24 amended—

25               (1) in paragraph (1)—

1 (A) by striking “and who is not the manu-  
2 facturer or an authorized distributor of record  
3 of such drug”;

4 (B) by striking “to an authorized dis-  
5 tributor of record or”; and

6 (C) by striking subparagraph (B) and in-  
7 serting the following:

8 “(B) The fact that a drug subject to subsection (b)  
9 is exported from the United States does not with respect  
10 to such drug exempt any person that is engaged in the  
11 business of the wholesale distribution of the drug from  
12 providing the statement described in subparagraph (A) to  
13 the person that receives the drug pursuant to the export  
14 of the drug.

15 “(C)(i) The Secretary shall by regulation establish re-  
16 quirements that supersede subparagraph (A) (referred to  
17 in this subparagraph as ‘alternative requirements’) to  
18 identify the chain of custody of a drug subject to sub-  
19 section (b) from the manufacturer of the drug throughout  
20 the wholesale distribution of the drug to a pharmacist who  
21 intends to sell the drug at retail if the Secretary deter-  
22 mines that the alternative requirements, which may in-  
23 clude standardized anti-counterfeiting or track-and-trace  
24 technologies, will identify such chain of custody or the  
25 identity of the discrete package of the drug from which

1 the drug is dispensed with equal or greater certainty to  
2 the requirements of subparagraph (A), and that the alter-  
3 native requirements are economically and technically fea-  
4 sible.

5 “(ii) When the Secretary promulgates a final rule to  
6 establish such alternative requirements, the final rule in  
7 addition shall, with respect to the registration condition  
8 established in clause (i) of section 804(c)(3)(B), establish  
9 a condition equivalent to the alternative requirements, and  
10 such equivalent condition may be met in lieu of the reg-  
11 istration condition established in such clause (i).”;

12 (2) in paragraph (2)(A), by adding at the end  
13 the following: “The preceding sentence may not be  
14 construed as having any applicability with respect to  
15 a registered exporter under section 804.”; and

16 (3) in paragraph (3), by striking “and sub-  
17 section (d)—” in the matter preceding subparagraph  
18 (A) and all that follows through “the term ‘whole-  
19 sale distribution’ means” in subparagraph (B) and  
20 inserting the following: “and subsection (d), the  
21 term ‘wholesale distribution’ means”.

22 (b) CONFORMING AMENDMENT.—Section 503(d) of  
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 353(d)) is amended by adding at the end the following:

1       “(4) Each manufacturer of a drug subject to sub-  
2 section (b) shall maintain at its corporate offices a current  
3 list of the authorized distributors of record of such drug.

4       “(5) For purposes of this subsection, the term ‘au-  
5 thorized distributors of record’ means those distributors  
6 with whom a manufacturer has established an ongoing re-  
7 lationship to distribute such manufacturer’s products.”.

8       (c) EFFECTIVE DATE.—

9           (1) IN GENERAL.—The amendments made by  
10 paragraphs (1) and (3) of subsection (a) and by sub-  
11 section (b) shall take effect on January 1, 2010.

12           (2) DRUGS IMPORTED BY REGISTERED IMPORT-  
13 ERS UNDER SECTION 804.—Notwithstanding para-  
14 graph (1), the amendments made by paragraphs (1)  
15 and (3) of subsection (a) and by subsection (b) shall  
16 take effect on the date that is 90 days after the date  
17 of enactment of this title with respect to qualifying  
18 drugs imported under section 804 of the Federal  
19 Food, Drug, and Cosmetic Act, as added by section  
20        4.

21           (3) HIGH-RISK DRUGS.—

22           (A) IN GENERAL.—Notwithstanding para-  
23 graph (1), the Secretary of Health and Human  
24 Services (referred to in this section as the “Sec-  
25 retary”) may apply the amendments made by

1 paragraphs (1) and (3) of subsection (a) and by  
2 subsection (b) before January 1, 2010, with re-  
3 spect to a prescription drug if the Secretary—

4 (i) determines that the drug is at high  
5 risk for being counterfeited; and

6 (ii) publishes the determination and  
7 the basis for the determination in the Fed-  
8 eral Register.

9 (B) PEDIGREE NOT REQUIRED.—Notwith-  
10 standing a determination under subparagraph  
11 (A) with respect to a prescription drug, the  
12 amendments described in such subparagraph  
13 shall not apply with respect to a wholesale dis-  
14 tribution of such drug if the drug is distributed  
15 by the manufacturer of the drug to a person  
16 that distributes the drug to a retail pharmacy  
17 for distribution to the consumer or patient, with  
18 no other intervening transactions.

19 (C) LIMITATION.—The Secretary may  
20 make the determination under subparagraph  
21 (A) with respect to not more than 50 drugs be-  
22 fore January 1, 2010.

23 (4) EFFECT WITH RESPECT TO REGISTERED  
24 EXPORTERS.—The amendment made by subsection

1 (a)(2) shall take effect on the date that is 90 days  
2 after the date of enactment of this title.

3 (5) ALTERNATIVE REQUIREMENTS.—The Sec-  
4 retary shall issue regulations to establish the alter-  
5 native requirements, referred to in the amendment  
6 made by subsection (a)(1), that take effect not later  
7 than—

8 (A) January 1, 2008, with respect to a  
9 prescription drug determined under paragraph  
10 (3)(A) to be at high risk for being counter-  
11 feited; and

12 (B) January 1, 2010, with respect to all  
13 other prescription drugs.

14 (6) INTERMEDIATE REQUIREMENTS.—With re-  
15 spect to the prescription drugs described under para-  
16 graph (5)(B), the Secretary shall by regulation re-  
17 quire the use of standardized anti-counterfeiting or  
18 track-and-trace technologies on such prescription  
19 drugs at the case and pallet level effective not later  
20 than January 1, 2008.

21 **SEC. \_\_\_\_ 7. INTERNET SALES OF PRESCRIPTION DRUGS.**

22 (a) IN GENERAL.—Chapter V of the Federal Food,  
23 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
24 ed by inserting after section 503A the following:



1 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

2 “(a) REQUIREMENTS REGARDING INFORMATION ON  
3 INTERNET SITE.—

4 “(1) IN GENERAL.—A person may not dispense  
5 a prescription drug pursuant to a sale of the drug  
6 by such person if—

7 “(A) the purchaser of the drug submitted  
8 the purchase order for the drug, or conducted  
9 any other part of the sales transaction for the  
10 drug, through an Internet site;

11 “(B) the person dispenses the drug to the  
12 purchaser by mailing or shipping the drug to  
13 the purchaser; and

14 “(C) such site, or any other Internet site  
15 used by such person for purposes of sales of a  
16 prescription drug, fails to meet each of the re-  
17 quirements specified in paragraph (2), other  
18 than a site or pages on a site that—

19 “(i) are not intended to be accessed  
20 by purchasers or prospective purchasers; or

21 “(ii) provide an Internet information  
22 location tool within the meaning of section  
23 231(e)(5) of the Communications Act of  
24 1934 (47 U.S.C. 231(e)(5)).

25 “(2) REQUIREMENTS.—With respect to an  
26 Internet site, the requirements referred to in sub-

1 paragraph (C) of paragraph (1) for a person to  
2 whom such paragraph applies are as follows:

3 “(A) Each page of the site shall include ei-  
4 ther the following information or a link to a  
5 page that provides the following information:

6 “(i) The name of such person.

7 “(ii) Each State in which the person  
8 is authorized by law to dispense prescrip-  
9 tion drugs.

10 “(iii) The address and telephone num-  
11 ber of each place of business of the person  
12 with respect to sales of prescription drugs  
13 through the Internet, other than a place of  
14 business that does not mail or ship pre-  
15 scription drugs to purchasers.

16 “(iv) The name of each individual who  
17 serves as a pharmacist for prescription  
18 drugs that are mailed or shipped pursuant  
19 to the site, and each State in which the in-  
20 dividual is authorized by law to dispense  
21 prescription drugs.

22 “(v) If the person provides for medical  
23 consultations through the site for purposes  
24 of providing prescriptions, the name of  
25 each individual who provides such con-

1                   sultations; each State in which the indi-  
2                   vidual is licensed or otherwise authorized  
3                   by law to provide such consultations or  
4                   practice medicine; and the type or types of  
5                   health professions for which the individual  
6                   holds such licenses or other authorizations.

7                   “(B) A link to which paragraph (1) applies  
8                   shall be displayed in a clear and prominent  
9                   place and manner, and shall include in the cap-  
10                  tion for the link the words ‘licensing and con-  
11                  tact information’.

12               “(b) INTERNET SALES WITHOUT APPROPRIATE  
13 MEDICAL RELATIONSHIPS.—

14               “(1) IN GENERAL.—Except as provided in para-  
15               graph (2), a person may not dispense a prescription  
16               drug, or sell such a drug, if—

17                   “(A) for purposes of such dispensing or  
18                   sale, the purchaser communicated with the per-  
19                   son through the Internet;

20                   “(B) the patient for whom the drug was  
21                   dispensed or purchased did not, when such  
22                   communications began, have a prescription for  
23                   the drug that is valid in the United States;

24                   “(C) pursuant to such communications, the  
25                   person provided for the involvement of a practi-

1           tioner, or an individual represented by the per-  
2           son as a practitioner, and the practitioner or  
3           such individual issued a prescription for the  
4           drug that was purchased;

5           “(D) the person knew, or had reason to  
6           know, that the practitioner or the individual re-  
7           ferred to in subparagraph (C) did not, when  
8           issuing the prescription, have a qualifying med-  
9           ical relationship with the patient; and

10           “(E) the person received payment for the  
11           dispensing or sale of the drug.

12       For purposes of subparagraph (E), payment is re-  
13       ceived if money or other valuable consideration is re-  
14       ceived.

15           “(2) EXCEPTIONS.—Paragraph (1) does not  
16       apply to—

17           “(A) the dispensing or selling of a pre-  
18           scription drug pursuant to telemedicine prac-  
19           tices sponsored by—

20           “(i) a hospital that has in effect a  
21           provider agreement under title XVIII of  
22           the Social Security Act (relating to the  
23           Medicare program); or

24           “(ii) a group practice that has not  
25           fewer than 100 physicians who have in ef-

1                   fect provider agreements under such title;  
2                   or

3                   “(B) the dispensing or selling of a pre-  
4                   scription drug pursuant to practices that pro-  
5                   mote the public health, as determined by the  
6                   Secretary by regulation.

7                   “(3) QUALIFYING MEDICAL RELATIONSHIP.—

8                   “(A) IN GENERAL.—With respect to  
9                   issuing a prescription for a drug for a patient,  
10                  a practitioner has a qualifying medical relation-  
11                  ship with the patient for purposes of this sec-  
12                  tion if—

13                       “(i) at least one in-person medical  
14                       evaluation of the patient has been con-  
15                       ducted by the practitioner; or

16                       “(ii) the practitioner conducts a med-  
17                       ical evaluation of the patient as a covering  
18                       practitioner.

19                   “(B) IN-PERSON MEDICAL EVALUATION.—

20                  A medical evaluation by a practitioner is an in-  
21                  person medical evaluation for purposes of this  
22                  section if the practitioner is in the physical  
23                  presence of the patient as part of conducting  
24                  the evaluation, without regard to whether por-

1           tions of the evaluation are conducted by other  
2           health professionals.

3           “(C) COVERING PRACTITIONER.—With re-  
4           spect to a patient, a practitioner is a covering  
5           practitioner for purposes of this section if the  
6           practitioner conducts a medical evaluation of  
7           the patient at the request of a practitioner who  
8           has conducted at least one in-person medical  
9           evaluation of the patient and is temporarily un-  
10          available to conduct the evaluation of the pa-  
11          tient. A practitioner is a covering practitioner  
12          without regard to whether the practitioner has  
13          conducted any in-person medical evaluation of  
14          the patient involved.

15          “(4) RULES OF CONSTRUCTION.—

16                 “(A) INDIVIDUALS REPRESENTED AS  
17                 PRACTITIONERS.—A person who is not a practi-  
18                 tioner (as defined in subsection (e)(1)) lacks  
19                 legal capacity under this section to have a  
20                 qualifying medical relationship with any patient.

21                 “(B) STANDARD PRACTICE OF PHAR-  
22                 MACY.—Paragraph (1) may not be construed as  
23                 prohibiting any conduct that is a standard prac-  
24                 tice in the practice of pharmacy.

1                   “(C)    APPLICABILITY    OF    REQUIRE-  
2                   MENTS.—Paragraph (3) may not be construed  
3                   as having any applicability beyond this section,  
4                   and does not affect any State law, or interpre-  
5                   tation of State law, concerning the practice of  
6                   medicine.

7                   “(c) ACTIONS BY STATES.—

8                   “(1) IN GENERAL.—Whenever an attorney gen-  
9                   eral of any State has reason to believe that the in-  
10                  terests of the residents of that State have been or  
11                  are being threatened or adversely affected because  
12                  any person has engaged or is engaging in a pattern  
13                  or practice that violates section 301(l), the State  
14                  may bring a civil action on behalf of its residents in  
15                  an appropriate district court of the United States to  
16                  enjoin such practice, to enforce compliance with such  
17                  section (including a nationwide injunction), to obtain  
18                  damages, restitution, or other compensation on be-  
19                  half of residents of such State, to obtain reasonable  
20                  attorneys fees and costs if the State prevails in the  
21                  civil action, or to obtain such further and other relief  
22                  as the court may deem appropriate.

23                  “(2) NOTICE.—The State shall serve prior writ-  
24                  ten notice of any civil action under paragraph (1) or  
25                  (5)(B) upon the Secretary and provide the Secretary

1 with a copy of its complaint, except that if it is not  
2 feasible for the State to provide such prior notice,  
3 the State shall serve such notice immediately upon  
4 instituting such action. Upon receiving a notice re-  
5 specting a civil action, the Secretary shall have the  
6 right—

7 “(A) to intervene in such action;

8 “(B) upon so intervening, to be heard on  
9 all matters arising therein; and

10 “(C) to file petitions for appeal.

11 “(3) CONSTRUCTION.—For purposes of bring-  
12 ing any civil action under paragraph (1), nothing in  
13 this chapter shall prevent an attorney general of a  
14 State from exercising the powers conferred on the  
15 attorney general by the laws of such State to con-  
16 duct investigations or to administer oaths or affir-  
17 mations or to compel the attendance of witnesses or  
18 the production of documentary and other evidence.

19 “(4) VENUE; SERVICE OF PROCESS.—Any civil  
20 action brought under paragraph (1) in a district  
21 court of the United States may be brought in the  
22 district in which the defendant is found, is an inhab-  
23 itant, or transacts business or wherever venue is  
24 proper under section 1391 of title 28, United States  
25 Code. Process in such an action may be served in



1       any district in which the defendant is an inhabitant  
2       or in which the defendant may be found.

3           “(5) ACTIONS BY OTHER STATE OFFICIALS.—

4               “(A) Nothing contained in this section  
5       shall prohibit an authorized State official from  
6       proceeding in State court on the basis of an al-  
7       leged violation of any civil or criminal statute of  
8       such State.

9               “(B) In addition to actions brought by an  
10       attorney general of a State under paragraph  
11       (1), such an action may be brought by officers  
12       of such State who are authorized by the State  
13       to bring actions in such State on behalf of its  
14       residents.

15       “(d) EFFECT OF SECTION.—This section shall not  
16       apply to a person that is a registered exporter under sec-  
17       tion 804.

18       “(e) GENERAL DEFINITIONS.—For purposes of this  
19       section:

20               “(1) The term ‘practitioner’ means a practi-  
21       tioner referred to in section 503(b)(1) with respect  
22       to issuing a written or oral prescription.

23               “(2) The term ‘prescription drug’ means a drug  
24       that is described in section 503(b)(1).

1           “(3) The term ‘qualifying medical relationship’,  
2           with respect to a practitioner and a patient, has the  
3           meaning indicated for such term in subsection (b).

4           “(f) INTERNET-RELATED DEFINITIONS.—

5           “(1) IN GENERAL.—For purposes of this sec-  
6           tion:

7                   “(A) The term ‘Internet’ means collectively  
8                   the myriad of computer and telecommunications  
9                   facilities, including equipment and operating  
10                  software, which comprise the interconnected  
11                  world-wide network of networks that employ the  
12                  transmission control protocol/internet protocol,  
13                  or any predecessor or successor protocols to  
14                  such protocol, to communicate information of  
15                  all kinds by wire or radio.

16                  “(B) The term ‘link’, with respect to the  
17                  Internet, means one or more letters, words,  
18                  numbers, symbols, or graphic items that appear  
19                  on a page of an Internet site for the purpose  
20                  of serving, when activated, as a method for exe-  
21                  cuting an electronic command—

22                          “(i) to move from viewing one portion  
23                          of a page on such site to another portion  
24                          of the page;

1 “(ii) to move from viewing one page  
2 on such site to another page on such site;  
3 or

4 “(iii) to move from viewing a page on  
5 one Internet site to a page on another  
6 Internet site.

7 “(C) The term ‘page’, with respect to the  
8 Internet, means a document or other file  
9 accessed at an Internet site.

10 “(D)(i) The terms ‘site’ and ‘address’, with  
11 respect to the Internet, mean a specific location  
12 on the Internet that is determined by Internet  
13 Protocol numbers. Such term includes the do-  
14 main name, if any.

15 “(ii) The term ‘domain name’ means a  
16 method of representing an Internet address  
17 without direct reference to the Internet Protocol  
18 numbers for the address, including methods  
19 that use designations such as ‘.com’, ‘.edu’,  
20 ‘.gov’, ‘.net’, or ‘.org’.

21 “(iii) The term ‘Internet Protocol num-  
22 bers’ includes any successor protocol for deter-  
23 mining a specific location on the Internet.

24 “(2) AUTHORITY OF SECRETARY.—The Sec-  
25 retary may by regulation modify any definition

1 under paragraph (1) to take into account changes in  
2 technology.

3 “(g) INTERACTIVE COMPUTER SERVICE; ADVER-  
4 TISING.—No provider of an interactive computer service,  
5 as defined in section 230(f)(2) of the Communications Act  
6 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services  
7 shall be liable under this section for dispensing or selling  
8 prescription drugs in violation of this section on account  
9 of another person’s selling or dispensing such drugs, pro-  
10 vided that the provider of the interactive computer service  
11 or of advertising services does not own or exercise cor-  
12 porate control over such person.”.

13 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of  
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 331) is amended by inserting after paragraph (k) the fol-  
16 lowing:

17 “(l) The dispensing or selling of a prescription drug  
18 in violation of section 503B.”.

19 (c) INTERNET SALES OF PRESCRIPTION DRUGS;  
20 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-  
21 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-  
22 NESSES.—In carrying out section 503B of the Federal  
23 Food, Drug, and Cosmetic Act (as added by subsection  
24 (a) of this section), the Secretary of Health and Human  
25 Services shall take into consideration the practices and

1 procedures of public or private entities that certify that  
2 businesses selling prescription drugs through Internet  
3 sites are legitimate businesses, including practices and  
4 procedures regarding disclosure formats and verification  
5 programs.

6 (d) REPORTS REGARDING INTERNET-RELATED VIO-  
7 LATIONS OF FEDERAL AND STATE LAWS ON DISPENSING  
8 OF DRUGS.—

9 (1) IN GENERAL.—The Secretary of Health and  
10 Human Services (referred to in this subsection as  
11 the “Secretary”) shall, pursuant to the submission  
12 of an application meeting the criteria of the Sec-  
13 retary, make an award of a grant or contract to the  
14 National Clearinghouse on Internet Prescribing (op-  
15 erated by the Federation of State Medical Boards)  
16 for the purpose of—

17 (A) identifying Internet sites that appear  
18 to be in violation of Federal or State laws con-  
19 cerning the dispensing of drugs;

20 (B) reporting such sites to State medical  
21 licensing boards and State pharmacy licensing  
22 boards, and to the Attorney General and the  
23 Secretary, for further investigation; and

24 (C) submitting, for each fiscal year for  
25 which the award under this subsection is made,

1 a report to the Secretary describing investiga-  
2 tions undertaken with respect to violations de-  
3 scribed in subparagraph (A).

4 (2) AUTHORIZATION OF APPROPRIATIONS.—For  
5 the purpose of carrying out paragraph (1), there is  
6 authorized to be appropriated \$100,000 for each of  
7 the fiscal years 2005 through 2007.

8 (e) EFFECTIVE DATE.—The amendments made by  
9 subsections (a) and (b) take effect 90 days after the date  
10 of enactment of this title, without regard to whether a  
11 final rule to implement such amendments has been pro-  
12 mulgated by the Secretary of Health and Human Services  
13 under section 701(a) of the Federal Food, Drug, and Cos-  
14 metic Act. The preceding sentence may not be construed  
15 as affecting the authority of such Secretary to promulgate  
16 such a final rule.

17 **SEC. \_\_\_\_ 8. PROHIBITING PAYMENTS TO UNREGISTERED**  
18 **FOREIGN PHARMACIES.**

19 (a) IN GENERAL.—Section 303 of the Federal Food,  
20 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by  
21 adding at the end the following:

22 “(g) RESTRICTED TRANSACTIONS.—

23 “(1) IN GENERAL.—The introduction of re-  
24 stricted transactions into a payment system or the

1 completion of restricted transactions using a pay-  
2 ment system is prohibited.

3 “(2) PAYMENT SYSTEM.—

4 “(A) IN GENERAL.—The term ‘payment  
5 system’ means a system used by a person de-  
6 scribed in subparagraph (B) to effect a credit  
7 transaction, electronic fund transfer, or money  
8 transmitting service that may be used in con-  
9 nection with, or to facilitate, a restricted trans-  
10 action, and includes—

11 “(i) a credit card system;

12 “(ii) an international, national, re-  
13 gional, or local network used to effect a  
14 credit transaction, an electronic fund  
15 transfer, or a money transmitting service;  
16 and

17 “(iii) any other system that is cen-  
18 trally managed and is primarily engaged in  
19 the transmission and settlement of credit  
20 transactions, electronic fund transfers, or  
21 money transmitting services.

22 “(B) PERSONS DESCRIBED.—A person re-  
23 ferred to in subparagraph (A) is—

24 “(i) a creditor;

25 “(ii) a credit card issuer;

1 “(iii) a financial institution;

2 “(iv) an operator of a terminal at  
3 which an electronic fund transfer may be  
4 initiated;

5 “(v) a money transmitting business;

6 or

7 “(vi) a participant in an international,  
8 national, regional, or local network used to  
9 effect a credit transaction, electronic fund  
10 transfer, or money transmitting service.

11 “(3) RESTRICTED TRANSACTION.—The term  
12 ‘restricted transaction’ means a transaction or trans-  
13 mittal, on behalf of an individual who places an un-  
14 lawful drug importation request to any person en-  
15 gaged in the operation of an unregistered foreign  
16 pharmacy, of—

17 “(A) credit, or the proceeds of credit, ex-  
18 tended to or on behalf of the individual for the  
19 purpose of the unlawful drug importation re-  
20 quest (including credit extended through the  
21 use of a credit card);

22 “(B) an electronic fund transfer or funds  
23 transmitted by or through a money transmit-  
24 ting business, or the proceeds of an electronic  
25 fund transfer or money transmitting service,



1 from or on behalf of the individual for the pur-  
2 pose of the unlawful drug importation request;

3 “(C) a check, draft, or similar instrument  
4 which is drawn by or on behalf of the individual  
5 for the purpose of the unlawful drug importa-  
6 tion request and is drawn on or payable at or  
7 through any financial institution; or

8 “(D) the proceeds of any other form of fi-  
9 nancial transaction (identified by the Board by  
10 regulation) that involves a financial institution  
11 as a payor or financial intermediary on behalf  
12 of or for the benefit of the individual for the  
13 purpose of the unlawful drug importation re-  
14 quest.

15 “(4) UNLAWFUL DRUG IMPORTATION RE-  
16 QUEST.—The term ‘unlawful drug importation re-  
17 quest’ means the request, or transmittal of a re-  
18 quest, made to an unregistered foreign pharmacy for  
19 a prescription drug by mail (including a private car-  
20 rier), facsimile, phone, or electronic mail, or by a  
21 means that involves the use, in whole or in part, of  
22 the Internet.

23 “(5) UNREGISTERED FOREIGN PHARMACY.—  
24 The term ‘unregistered foreign pharmacy’ means a

1 person in a country other than the United States  
2 that is not a registered exporter under section 804.

3 “(6) OTHER DEFINITIONS.—

4 “(A) CREDIT; CREDITOR; CREDIT CARD.—

5 The terms ‘credit’, ‘creditor’, and ‘credit card’  
6 have the meanings given the terms in section  
7 103 of the Truth in Lending Act (15 U.S.C.  
8 1602).

9 “(B) ACCESS DEVICE; ELECTRONIC FUND  
10 TRANSFER.—The terms ‘access device’ and  
11 ‘electronic fund transfer’—

12 “(i) have the meaning given the term  
13 in section 903 of the Electronic Fund  
14 Transfer Act (15 U.S.C. 1693a); and

15 “(ii) the term ‘electronic fund trans-  
16 fer’ also includes any fund transfer covered  
17 under Article 4A of the Uniform Commer-  
18 cial Code, as in effect in any State.

19 “(C) FINANCIAL INSTITUTION.—The term  
20 ‘financial institution’—

21 “(i) has the meaning given the term  
22 in section 903 of the Electronic Transfer  
23 Fund Act (15 U.S.C. 1693a); and

1 “(ii) includes a financial institution  
2 (as defined in section 509 of the Gramm-  
3 Leach-Bliley Act (15 U.S.C. 6809)).

4 “(D) MONEY TRANSMITTING BUSINESS;  
5 MONEY TRANSMITTING SERVICE.—The terms  
6 ‘money transmitting business’ and ‘money  
7 transmitting service’ have the meaning given  
8 the terms in section 5330(d) of title 31, United  
9 States Code.

10 “(E) BOARD.—The term ‘Board’ means  
11 the Board of Governors of the Federal Reserve  
12 System.

13 “(7) POLICIES AND PROCEDURES REQUIRED TO  
14 PREVENT RESTRICTED TRANSACTIONS.—

15 “(A) REGULATIONS.—The Board shall  
16 promulgate regulations requiring—

17 “(i) an operator of a credit card sys-  
18 tem;

19 “(ii) an operator of an international,  
20 national, regional, or local network used to  
21 effect a credit transaction, an electronic  
22 fund transfer, or a money transmitting  
23 service;

24 “(iii) an operator of any other pay-  
25 ment system that is centrally managed and

1 is primarily engaged in the transmission  
2 and settlement of credit transactions, elec-  
3 tronic transfers or money transmitting  
4 services where at least one party to the  
5 transaction or transfer is an individual;  
6 and

7 “(iv) any other person described in  
8 paragraph (2)(B) and specified by the  
9 Board in such regulations,  
10 to establish policies and procedures that are  
11 reasonably designed to prevent the introduction  
12 of a restricted transaction into a payment sys-  
13 tem or the completion of a restricted trans-  
14 action using a payment system

15 “(B) REQUIREMENTS FOR POLICIES AND  
16 PROCEDURES.—In promulgating regulations  
17 under subparagraph (A), the Board shall—

18 “(i) identify types of policies and pro-  
19 cedures, including nonexclusive examples,  
20 that shall be considered to be reasonably  
21 designed to prevent the introduction of re-  
22 stricted transactions into a payment sys-  
23 tem or the completion of restricted trans-  
24 actions using a payment system; and

1 “(ii) to the extent practicable, permit  
2 any payment system, or person described  
3 in paragraph (2)(B), as applicable, to  
4 choose among alternative means of pre-  
5 venting the introduction or completion of  
6 restricted transactions.

7 “(C) NO LIABILITY FOR BLOCKING OR RE-  
8 FUSING TO HONOR RESTRICTED TRANS-  
9 ACTION.—

10 “(i) IN GENERAL.—A payment sys-  
11 tem, or a person described in paragraph  
12 (2)(B) that is subject to a regulation  
13 issued under this subsection, and any par-  
14 ticipant in such payment system that pre-  
15 vents or otherwise refuses to honor trans-  
16 actions in an effort to implement the poli-  
17 cies and procedures required under this  
18 subsection or to otherwise comply with this  
19 subsection shall not be liable to any party  
20 for such action.

21 “(ii) COMPLIANCE.—A person de-  
22 scribed in paragraph (2)(B) meets the re-  
23 quirements of this subsection if the person  
24 relies on and complies with the policies and  
25 procedures of a payment system of which

1 the person is a member or in which the  
2 person is a participant, and such policies  
3 and procedures of the payment system  
4 comply with the requirements of the regu-  
5 lations promulgated under subparagraph  
6 (A).

7 “(D) ENFORCEMENT.—

8 “(i) IN GENERAL.—This section shall  
9 be enforced by the Federal functional regu-  
10 lators and the Federal Trade Commission  
11 under applicable law in the manner pro-  
12 vided in section 505(a) of the Gramm-  
13 Leach-Bliley Act (15 U.S.C. 6805(a)).

14 “(ii) FACTORS TO BE CONSIDERED.—  
15 In considering any enforcement action  
16 under this subsection against a payment  
17 system or person described in paragraph  
18 (2)(B), the Federal functional regulators  
19 and the Federal Trade Commission shall  
20 consider the following factors:

21 “(I) The extent to which the pay-  
22 ment system or person knowingly per-  
23 mits restricted transactions.

1                   “(II) The history of the payment  
2                   system or person in connection with  
3                   permitting restricted transactions.

4                   “(III) The extent to which the  
5                   payment system or person has estab-  
6                   lished and is maintaining policies and  
7                   procedures in compliance with regula-  
8                   tions prescribed under this subsection.

9                   “(8) TRANSACTIONS PERMITTED.—A payment  
10                  system, or a person described in paragraph (2)(B)  
11                  that is subject to a regulation issued under this sub-  
12                  section, is authorized to engage in transactions with  
13                  foreign pharmacies in connection with investigating  
14                  violations or potential violations of any rule or re-  
15                  quirement adopted by the payment system or person  
16                  in connection with complying with paragraph (7). A  
17                  payment system, or such a person, and its agents  
18                  and employees shall not be found to be in violation  
19                  of, or liable under, any federal, state or other law by  
20                  virtue of engaging in any such transaction.

21                  “(9) RELATION TO STATE LAWS.—No require-  
22                  ment, prohibition, or liability may be imposed on a  
23                  payment system, or a person described in paragraph  
24                  (2)(B) that is subject to a regulation issued under  
25                  this subsection, under the laws of any state with re-

1       spect to any payment transaction by an individual  
2       because the payment transaction involves a payment  
3       to a foreign pharmacy.

4               “(10) TIMING OF REQUIREMENTS.—A payment  
5       system, or a person described in paragraph (2)(B)  
6       that is subject to a regulation issued under this sub-  
7       section, must adopt policies and procedures reason-  
8       ably designed to comply with any regulations re-  
9       quired under paragraph (7) within 60 days after  
10      such regulations are issued in final form.”.

11      (b) EFFECTIVE DATE.—The amendment made by  
12      this section shall take effect on the day that is 90 days  
13      after the date of enactment of this title.

14      (c) IMPLEMENTATION.—The Board of Governors of  
15      the Federal Reserve System shall promulgate regulations  
16      as required by subsection (g)(7) of section 303 of the Fed-  
17      eral Food, Drug, and Cosmetic Act (21 U.S.C. 333), as  
18      added by subsection (a), not later than 90 days after the  
19      date of enactment of this title.

20   **SEC.    9.  IMPORTATION  EXEMPTION  UNDER  CON-**  
21                               **TROLLED SUBSTANCES IMPORT AND EXPORT**  
22                               **ACT.**

23      Section 1006(a)(2) of the Controlled Substances Im-  
24      port and Export Act (21 U.S.C. 956(a)(2)) is amended  
25      by striking “not import the controlled substance into the



1 United States in an amount that exceeds 50 dosage units  
2 of the controlled substance.” and inserting “import into  
3 the United States not more than 10 dosage units com-  
4 bined of all such controlled substances.”.